

Book 5: Summary Submission to President Joseph Biden on January 18, 2025

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Charles H. Andrus, M.D., F.A.C.S.

NIH NIAID Case file #12276

April 1, 2025

Over the course of the last five years under NIH NIAID case file number 12276, I have submitted my concerns regarding our treatment of COVID-19, RSV and measles to many within the federal government.⁴⁻¹¹ When one looks at my writings over that time period, they reflect the inherent misdirection of our thinking or lack of a unification of thought rationale with regards to Clinical Immunology. In medical school during my basic science years, I was exposed to the concept of immunology and its applications in medicine at the time. My initiation into the medical profession was at the time of the start of the pandemic of human immunodeficiency virus (HIV), the development in the techniques of DNA sequencing, and the elaboration of DNA by polymerase chain reaction (PCR). Molecular biology concepts were in their infancy compared to that which we know today. Many of the facets of the seemingly divergent aspects of immunology were outwardly and apparently divergent in application and implementation in Clinical Medicine with our *de facto* neophytic comprehension. Clinical (therapeutic) Immunology at the time of my education was foundationally divided into:

Active Immunization (prophylaxis by vaccination) is the provision of exogenous antigens to the individual to promote the body to produce acutely, specific, endogenous immunoglobulins against the presented antigens with, over roughly 2 week course, the production of IgGs with the resultant long-term development of plasma cells that retain the memory of the exogenous antigens for years to come. As the development of plasma memory cells are long-term, vaccination (possibly with boosters) can be for life, e.g.: smallpox (and now monkey pox), DPT, MMR, polio, RSV, chickenpox, hepatitis B vaccines, etc.

Versus

Passive Immunization (treatment by convalescent plasma and sera--and today monoclonal antibodies, etc.) is the provision of exogenous antibodies to the individual to address acutely and immediately with exogenous IgGs to specific antigens of infections, toxins, and envenomations in the individual. While accomplishing an immediate treatment during the early phase (viremia) of the disease, these administered exogenous IgGs will have diminishing effectiveness in the individual's serum over about 2 months as the half-life of these IgGs are about 20-30 days, e.g.: Pasteur's rabies "vaccine", hyperTet, RhoGam, IVIGs, monoclonal antibodies and antibody cocktails, gammaglobulins, e.g.: GamaSTAN® S/D for measles, anti-bacteria and anti-viral immunoglobulins, and anti-snake and anti-insect venoms, etc.

Thus, while **Active Immunization** in the individual is relatively long-lasting and protective in the immunocompetent individual, **Passive Immunization** in the unvaccinated, the under-vaccinated, and the immunologically-incompetent individual is a relatively short-lived therapeutic agent but can be a life-saving treatment for exposed or infected individuals when given shortly after exposure or diagnosis. The euphemistic¹² confusion in Medicine today, though, promotes vaccination (*active immunization*) as a treatment--which it is not; and, the only always immediately available, continually updating specific *passive immunological* source is some form of convalescent plasma or sera from a recovered, previously-infected individual who previously contracted the disease and survived. Throughout this *Book 5: Summary Submission to President Joseph Biden on January 18, 2025*¹⁰, is a collections of communications, articles, and analyses regarding the early treatment within 72 hours of diagnosis (phase of viremia) of the coronavirus, SARS-CoV-2, COVID-19 with **Passive Immunization**, e.g.: Convalescent plasma, monoclonal antibodies, etc. and the antiviral Remdesivir (Veklury). Book 6¹¹ goes one step further elaborating on the fundamental concepts of **Active Immunization** (endogenous immunoglobulins / prophylaxis / vaccination) versus **Passive Immunization** (exogenous immunoglobulins / treatment and post exposure prophylaxis) in the context of the present-day, public-health-visible viral Infections of measles (*Rubeola*), Respiratory Syncytial Virus (RSV), and coronavirus, SARS-CoV-2, COVID-19. The fundamental distinctions of Clinical Immunology: 1.) **Treatment with Passive Immunization** and 2.) **Prophylaxis with Active Immunization** have all but been dismissed and forgotten in our seemingly present Machiavellian-like societal¹³ mindset consistent with *the end justifies the means* and where the *ad hominem* attack¹⁴⁻¹⁶ has become paramount in our daily politics and media. These fundamental clinical principles of *Passive Immunization*: (1) date back to Pasteur and von Behring which today have been discarded in our present approach to unvaccinated or immune-incompetent individuals; (2) have successfully been implemented in the acute, early treatment of bacterial and viral infections, toxins, and envenomations for greater than century; and (3) should be the foundational cornerstones in our immunotherapeutic treatment of infectious diseases to all those acutely afflicted and are unvaccinated, under-vaccinated, or immunocompromised.

Additionally:

A. Statistics: In regards to COVID-19, SARS-CoV-2 and published RCT trials with mortality as their primary end-point, all RCTs have been underpowered statistically¹⁷⁻¹⁹ over the last five years due to the substantial, upwardly increasing mortality rate (~0.5% per year increasing mortality by age) after age 49 as derived from the published CDC data from 2020-early 2021 that were collected and reported by the CDC prior to or just at the initiation of the COVID-19 Vaccinations to the U.S.A. public.
https://web.archive.org/web/20210217175653/https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAge: 50 – 90+ years of age: Mortality rate (y) = 0.0052 (x) – 0.1305 $r^2 = 0.99$
*The Graphs used in the derivation of this aforementioned equation can be found on page 341 in this Book 6*¹¹ 0.9 Attachment VIII Pg 24 Graph IV from Generalized Dismissal of Early Treatment with Passive Immunization and Antivirals

With such a dramatic increase in mortality rate for COVID-19 per year, a large number of subjects in each age subgroup are necessary to appropriately compare the effectiveness of a therapy in promoting survival.^{4,7-11}

B. March 29, 2025: On Friday evening, 3/28/2025, it was announced that Peter Marks, M.D., PhD resigned from the FDA as the “top vaccine scientist.”^{20,21} This statement of his being the “top vaccine scientist” was *palteringly* inaccurate as Dr. Marks was the **Director of the FDA’s Center for Biologics Evaluation and Research (CBER)** which meant that he had overview responsibilities regarding all

Biologics including those of *Active Immunization* (vaccines) and *Passive Immunization* (all exogenous immunoglobulins used to treat viruses and bacteria, toxins, and envenomations).

Please note: My Letter (pages e11-e74 of Book 6¹¹) in which I suggested to HHS Secretary Robert F. Kennedy that he consult Dr. Marks and Dr. Farley was mailed on 03/22/2025 via USPS Priority Mail. It was reported on 3/29/2025, in USPS tracking that it had yet to be delivered to Secretary Kennedy as is documented by the USPS tracking #9405530109355121386196. Such documentation implies that my recommendation that Secretary Kennedy speak with Dr. Marks (page e19 of Book 6¹¹) will arrive after he resigned or was fired.^{20,21} It is likely, though, that Secretary Kennedy was given a copy of my letter prior to Dr. Marks' separation from the position of Director of the FDA's Center for Biologics Evaluation and Research (CBER) as I had attached a copy of my letter to Secretary Kennedy to an e-mail sent to Acting Surgeon General Denis Hinton, US PHS Rear Admiral, MS, RN, FAAN that was dated and timed: Monday, March 24, 2025 at 03:55 PM CDT (page e345 of Book 6¹¹) which was thus delivered to the Office of the Surgeon General to the e-mail address of: surgeongeneral@hhs.gov four days before Dr. Marks' resignation or firing as the Director of CBER.

THIS IS EXTREMELY IMPORTANT as the *Passive Immunity* agent, GamaSTAN® S/D, a gamma globulin agent is being ignored even though it was approved by the FDA in 1944; and the present upgraded form of GamaSTAN® S/D is still approved today in the treatment within six days of exposure to Hepatitis A and measles (Rubeola) as noted in BOOK 6¹¹ and is the Public Health Recommendations of several states: California, New York, Minnesota and the country of Canada. In all the present discussions in the media today, nowhere is it stated that those exposed to measles who are unvaccinated, under-vaccinated, or immunocompromised should be administered GamaSTAN® S/D or IVIG / Convalescent Plasma specific for measles (Rubeola)—BUT THEY ALL SHOULD BE TREATED THIS WAY!

THIS IS HOW THE PRESENT MEASLES OUTBREAKS THROUGHOUT THE U.S.A. SHOULD BE TREATED!

Respectfully,

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Retired, Physician and Surgeon, Veterans Health Administration, USDVA
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NIH NIAID #12276

January 18, 2025

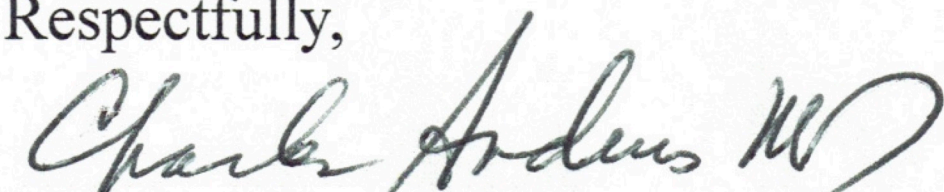
President Joseph Biden
The White House
1600 Pennsylvania Avenue NW
Washington, DC. 20500

Dear President Biden:

As a former Physician and Surgeon of the U.S. Department of Veterans Affairs and Professor of Surgery, Saint Louis University School of Medicine, I have attempted to communicate with the NIH, the FDA, the VA, and *The White House* regarding **early treatment** (within 72 hours of diagnosis of COVID-19 infection) in deference to prophylaxis (vaccination) for COVID-19. On July 7, 2023, you responded with the following letter: <https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attempt>

While it was a very kind acknowledgment letter, the issues I raised within U.S. Medicine remain unaddressed. Thus, attached with this cover letter is a first draft of my planned submission to *The New England Journal of Medicine*. [USPS Tracking# 9405 5036 9930 0739 9678 19] While the Editors may or may not accept it for publication, I see it as my duty to U.S. Medicine and our country to submit it.

Respectfully,


Charles Andrus, M.D., F.A.C.S.

Name	Date Modified	Size	Kind
0.1 2025-01-18 Generalized Dismissal of Early Treatment with Passive Immunization and Antivirals	Today at 9:41AM	10.3 MB	Microso...(.docx)
0.2 Attachment I Euphemistical Obfuscation in Clinical Medicine	Dec 13, 2024 at 5:52 AM	301 KB	Microso...(.docx)
0.3 Attachment II Submissions to the Internet Archive	Dec 13, 2024 at 5:55 AM	273 KB	Microso...(.docx)
0.4 Attachment III Reductio ad Absurdum	Dec 13, 2024 at 5:57 AM	4.8 MB	Microso...(.docx)
0.5 Attachment IV Validation letter from the NIH NIAID establishing NIAID Case # 12276	Dec 13, 2024 at 6:17 AM	8.7 MB	Microso...(.docx)
0.6 Attachment V 1977 NEJM letter of Case of Chronic Denial with Alfred Gilman response	Dec 13, 2024 at 6:03 AM	921 KB	Microso...(.docx)
0.7 Attachment VI Tables re Sources Definitions and Statistics	Dec 13, 2024 at 6:06 AM	627 KB	Microso...(.docx)
0.8 Attachment VII Letters to Members of Congress and Pres Trump 8_23_2020 and 8_28_2020	Dec 12, 2024 at 10:20 AM	3.4 MB	Microso...(.docx)
0.9 Attachment VIII 08 076.0 2021-09-19 Tragedy of Electronic Overwriting	Dec 31, 2024 at 11:29 AM	635 KB	Microso...(.docx)
1.0 REFERENCES of ATTACHMENTS I - VIII	Dec 13, 2024 at 11:48 AM	264 KB	Microso...(.docx)
2.1 Table 1- Digital vs. Analog—Yes, No, Maybe in Medicine and Treatment of Covid-19	Dec 13, 2024 at 6:33 AM	2.1 MB	Microso...(.docx)
2.2 Definitions_Fundamentals_Legal_Mandates background	Dec 13, 2024 at 6:13 AM	33 KB	Microso...(.docx)
2.3 2024-11-23 Tables 2-6	Dec 12, 2024 at 10:44 AM	5.9 MB	Microso...(.docx)
2.4 References for Tables 1 – 6	Dec 13, 2024 at 6:39 PM	2.1 MB	Microso...(.docx)
3 2024-11-23 Some Pertinent Transcripts and Excerpts	Nov 23, 2024 at 6:25 AM	2.9 MB	Microso...(.docx)

Generalized Dismissal of Early Treatment with *Passive Immunization* and Antivirals (Not Prophylaxis/*Active Immunization*) in Persons Infected with COVID-19

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U.S. Office of Special Counsel, files MA-00-1107, DI-00-1147

U.S. Court of Appeals for the Federal Circuit, *Andrus v VA*,

Case# 03-3162 (EEOC case 210A36145X)

NIAID Case #12276, U.S. National Institutes of Health, National
Institute of Allergy and Infectious Diseases (NIAID)

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Draft of January 18, 2025

Abstract:

Introduction: On March 2, 2020, in the Cabinet Room, *The White House* COVID-19 Commission was announced establishing a collaboration among the Commission, key-players in U.S. Medicine, and the Pharmaceutical and Biological Companies. Throughout America's four years of addressing the COVID-19 epidemic before the public, official plans based on future prophylaxis of the population (Active Immunization) were promoted as paramount in deference to the immediate treatment of all COVID-19-infected individuals within 72 hours of diagnosis during the viremic phase of the disease with immunoglobulins (Passive Immunization) and antivirals. During March and April 2020, a series of misdirected assertions resulted in a confused, arbitrary, bureaucratic, leaderless methodology: (1) non-sensical euphemistic definition of "*Passive Vaccination*" (3/2/2020); (2) Public Health Emergency declaration (3/13/2020); (3) *de facto* suspension of individual patient's rights under EMTALA (3/17/2020); (4) the Surgeon General's PSA advising infected patients to avoid hospitals (3/18/2020); (5) instead of designating COVID-19 Convalescent Plasma (CCP) as biosimilar biologic to Fresh Frozen Plasma (FFP), the FDA designated CCP as Investigational (3/24/2020) and incorrectly established "eligibility criteria" resulting in *de facto* rationing CCP (and all other treatments) from most of the acutely infected population; (6) with the electronic overwriting of the 3/24/2020, the FDA, the NIH, and the VA implement across-the-board the subliminal practice of electronic overwriting and URL sunseting which are broad violations of the Sarbanes/Oxley Act of 2002, 18 U.S.C. §1512(c)(1); and (7) the initiation of the FDA/Mayo Clinic CCP Express Access (*Compassionate Use*) Program (4/1/2020) (with mainly >100,000 treatments during the late-in-disease/non-viremic phase) thus precluding official completion of Phase I safety studies and preventing individual-infected patient's rights to ask for CCP off-protocol under The Right to Try Act of 2018, PL-115-176, 21 U.S.C. 360bbb-0a.

Methods: (1) The vast majority of documentation covered by this summary paper was submitted to NIH NIAID case file #12276 which was established in a response letter of 6/10/2020, directed by Dr. Fauci is discoverable under the Freedom of Information Act, 5 U.S.C. 552. (2) In-depth summaries —especially Books 1, 3, & 4-- can be found by a search of the *Internet Archive Advanced Search* by entering **VA** in "Any field" and **Charles Andrus** in "Creator". (3) Examples of the illegality of Electronic Overwriting and URL sunseting as violations of the Sarbanes-Oxley Act of 2002, 18 U.S.C. §1512(c)(1) are delineated throughout this paper. (4) Fact checking and identifying misstatements, misinterpretations, and misrepresentations of official definitions that have resulted in *paltering* defilements, violations of Federal law, and lies of commission and omission are key components of the Results and Discussion sections of this paper. (5) Statistical analyses were performed on (a) the *ex post facto* November 18, 2021 *NEJM* article: Korley, *et al.*: Early convalescent plasma for high-risk outpatients with Covid-19 and (b) the FDA documentation of improved survival reports due to CCP when administered early-in-the-individual's disease-course of August 23, 2020 and September 23, 2020, contradicting (c) the FDA subliminal withdrawal of CCP availability and usage subsequent to the NIH funded SIREN-C3PO report without credible background documentation of March 2021.

Results: Korley, *et al*, of November 2021, published in the *New England Journal of Medicine* is a misleading, *post facto*, statistically corrupt analysis of the early administration of CCP (within 72 hours of diagnosis of COVID-19 in the individual patient) as was put forth in March 2021, from the NIH funded SIREN-C3PO randomized controlled study without documentation at that time. The FDA documentation on August 23, 2020 and September 23, 2020, correctly reported that when CCP was given to ≤ 80 year-old patients within 72 hours of new COVID-19 documentation, there was significant decreased mortality and increased survival in all those treated.

Discussion: Flagrant electronic overwriting of official governmental policies and documentation and discontinuation of direct access to URLs regarding critical points in the administration of *Passive Immunization* (CCP) and antivirals within 72 hours of diagnosis of COVID-19 infection led to rejection of long-term, foundational clinical therapeutic guidelines. With regards to the presentation of all future novel viruses, U.S. Medicine has incorrectly rewritten history and condemned our society to a focus on only prophylaxis (*Active Immunization*) and not immediate treatment to all infected with a novel virus.

Introduction:

With the onset of the world-wide COVID-19 pandemic, the vast majority of countries were affected throughout the course of 2020-2022 with a prevalence and mortality of each country decreasing approaching an asymptotically long-term endemic nadir. While important (but-treatment-distracting) debates raged throughout the World regarding (Personal Protective Equipment) PPE^{1,2}, isolation / quarantine methodologies³, and therapeutic supportive care.⁴ The underlying medical urgency throughout the world was the immediate development of effective therapeutics for (1) the treatment of the acutely infected individuals and (2) prophylaxis for the future across all populations.⁵⁻⁹ Unfortunately, the focus in the United States publicly became an almost exclusive emphasis on prophylaxis—**Active Immunization** / vaccination¹⁰⁻¹⁴ euphemistically¹⁵ confusing vaccine prophylaxis with treatment with **Passive Immunization** and **Antivirals** of active disease bordering on subliminal infected-patient abandonment.

One of the first officially public meetings by the government, medical academia, and pharmaceutical industry to address the pending COVID-19 American epidemic occurred in the Cabinet Room of the *The White House* on March 2, 2020.¹⁶ In attendance were President Donald Trump, Vice-President Michael Pence, and some prominent representatives from U.S. Medicine, Academia, and Pharmacologic and Biologic Companies. (**Transcript 3**) The uniquely historical, traditionally-indispensable groups usually in the forefront in the combating of an epidemic of an immunologically-novel virus that was absent from that meeting of March 2, 2020, were representatives of the Association of American Blood Banks (AABB) and the American Red Cross (ARC).¹⁷⁻²¹ As in the early stages of several epidemics of immunologically-novel viruses during the 20th century, the AABB and the ARC should have become immediately the initial facilitators of the collection, processing, and distribution immunotherapy as an early treatment (< 72 hours from diagnosis) (not as prophylaxis) with the initial immunotherapy: convalescent plasma. A national plasma-collection-drive to provide for the stockpiling and distribution to all infected individuals within 72 hours of diagnosis with COVID-19 Convalescent Plasma (CCP)—a polyclonal *Passive Immunization* agent—should have been initiated.²²⁻²⁵ Along with the declaration of a Public Health Emergency (PHE) of March 13, 2020²⁶, there should have been a Presidential nation-wide mandate for the collection, processing, distribution, and early treatment-administration within 72 hours of diagnosis to all individuals infected with COVID-19 with convalescent plasma (CCP) and/or serum.

Throughout the twentieth century, prompted by the scientific research investigations in the late 19th century like Pasteur's administration to Joseph Meister of the rabies vaccine (1885)²⁷⁻²⁹ and the resultant awarding of the first Nobel Prize in Physiology or Medicine (1901) to Emil Adolf von Behring for his work on serum therapy (e.g.: against diphtheria and tetanus)³⁰⁻³², **Passive Immunization** has been utilized for over a century to provide exogenous antibodies: (1) in the acute treatment of viral and bacterial diseases and infectious epidemics and endemics; (2) in the neutralization of snake and insect envenomations; (3) in the prevention of sensitization of postpartum Rh negative mothers within 72 hours of delivery or miscarriage of a Rh positive child thus markedly diminishing in the mother's future possibility of delivering a subsequent offspring suffering from the major cause of hydrops fetalis in future pregnancies and thus

historically decreasing the prevalence of neonate mortality; (4) in the immunological supplementation of immunodeficient patients and in the treatment of autoimmune diseases; treatment in the attenuation of transplantation rejection; and, (5) as recurrent-monthly prophylaxis, in such viral diseases as RSV in high risk infants.³³⁻⁴⁷

In the approach to the treatment of acutely-infected (within <72 hours) individuals with coronavirus, SARS-CoV-2, COVID-19 in the U.S.A. as directed by U.S. Medicine (i.e.: clinical, research, and academic), though, the medical practices advocated by the U.S. Department of Health and Human Services, the U.S. Department of Veterans Affairs, and all of U.S. Medicine were essentially the nihilistic abandonment of exogenous polyclonal antibodies early (within <72 hours from diagnosis) with the ***Passive Immunological treatment*** with CCP in every acutely-infected individual. At best, this resultant confusion promoted as a massively-disorganized, leaderless disservice to the individual COVID-19 infected immunologically-COVID-19-naïve patient. A contemporary, parallel-historical, and ongoing example of this simplistic disorganization is the addressing of Respiratory Syncytial Virus (RSV) over the last quarter of a century by restricting and rationing of the monoclonal antibody palivizumab (Synagis) to only high-risk infants and neonates.⁴⁷ (**Attachment I**) U.S. Medicine's addressing of coronavirus, SARS-CoV-2, COVID-19, like RSV, is tainted throughout by ***Lies of Omission*** and ***Paltering***.⁴⁸⁻⁵²

PALTERING as defined by the Merriam-Webster dictionary as: "to act insincerely or deceitfully: **EQUIVOCATE**." Probably a more contemporary, daily application in American society today would be: "***Paltering*** is the active use of truthful statements to convey a misleading impression."

A prime example of a seemingly, innocuous ***paltering*** statement at present time on television is that of Pfizer, Inc.'s aggressive marketing⁵³ in the American media of their *Active Immunizational* RSV vaccine, ABRYSSVO:

From this can't miss moment. To this, hello new grandfather moment. To that whatever this is moment. Your moments are worth protecting against RSV. If you're 75 or older or 60 or older with a chronic condition like asthma COPD heart disease or severe diabetes, you're at higher risk of ending up in the hospital from RSV and **there are no RSV prescription treatments**. Check eligibility and schedule your RSV vaccine at VaxAssist.com. Moments like this matter.

Pfizer Outdo Yesterday. <https://www.ispot.tv/ad/fA4n/pfizer-inc-your-moments-are-worth-protecting>

As there are no FDA approved *prescriptive treatments* due to an *arbitrarily FDA-rationed prescriptive prophylaxis only* with the passive immunologic agent/monoclonal antibody: palivizumab (Synergis),⁴⁷ such paltering pharmaceutical marketing methodology as above⁵⁴⁻⁵⁸ of the *Active Immunizational*, prophylactic vaccine agent, ABRYSSVO, for only those >60 years old (between 2022-2024) was conjointly consistent and a continuation of the FDA's 25-year confining approvals and therapeutic restrictions / rationing of the *Passive Immunization* of the monoclonal antibody, palivizumab (Synagis). Synagis was restricted over a quarter of a century to the administration as a prophylactic regime only to non-infected, high-risk neonates and infants against Respiratory Syncytial Virus (RSV).⁴⁷ As of October 2024, this seemingly, innocuous *de facto* restrictive, rationing, collaboration between the FDA and the pharmaceutical industry has been selectively extended to promote the parasitic-marketing restriction of the RSV

vaccine Abrysvo (*Active Immunization*) to only select “high-at-risk” subgroups between 18 and 59 years of age and all those 60 years of age and over while dismissing any appropriate *Active Immunization of the entire U.S. population* regardless of age, concomitant disease, or other non-RSV conditions.⁵⁹ Coherent with what has been legally mandated for decades in all 50 states and American protectorates for all children at ages 1 and 6 years of life, the vaccination against viruses of the Paramyxoviridae family⁶⁰ by MMR inoculations (i.e.: the MMR is the vaccine against measles, mumps, and rubella)⁶¹, is routine. Vaccination against RSV (also of the Paramyxoviridae family) in all the children would diminish, if not virtually eliminate, the vector-effect within the “herd”⁶² --BUT this, at present, is not even contemplated in the United States. Failing to consider any treatment of acutely infected-RSV-individuals regardless of age with *Passive Immunization* and/or the RSV specific antiviral rabivirin^{63,64} when RSV is acutely contracted by the individual patient and limiting prophylaxis with *Active Immunization* regardless of age of the entire American population is clinically ignorant and should probably be considered an unethical policy of the FDA bordering on the likes of the Tuskegee Syphilis Project—but now, at a national level.^{65,66}

Throughout all walks of life, ***Paltering*** has become pervasive in U.S. society today. (**Attachment I**) The promulgation of misinformation and the disconnected distribution and marketing of disjointed, fragmented information, benefits few at the expense of many--privileged individuals, stockholders, and/or companies. ***Paltering advertising*** and ***promotion*** are overwhelmingly detrimental to society as a whole. ***Paltering*** has contributed to misinformation and ignorance of the whole whether it be in U.S. business, U.S. academia, U.S. politics, U.S. Medicine, etc. In U.S. Medicine today, our traditional safeguards (e.g.: the FDA^{67,68}, the CDC, the USPHS, the NIH, the VA, Academic Medicine, Editorial peer-review, etc.) that have ostensibly endorsed honesty as their foundational cornerstones and tacitly promoted: *Vincit Omnia Veritas*- Truth Conquers All^{69,70, Attachment VIII}, **HAVE FAILED** us! In short, the American public is being treated like mushrooms -- being kept in the dark and being fed a bunch of manure (regardless how purified or rarefied it may be).⁷¹

In an attempt to reconcile and breach the clinical-application chasms among U.S. medical research, U.S. federal funding and support, and the daily practice of Medicine⁷²—*vis-à-vis* for each and every individual patient involved in a Randomized Controlled Trial (RCT)⁷³⁻⁷⁸, Dr. Jeffrey Drazen, former editor-in-chief of *The New England Journal of Medicine* has suggested a transparency in clinical trial data with availability for all.^{79,80} Contradicting that which Dr. Drazen advocated in a NEJM interview⁷⁹, regarding the NEJM’s adherence to the integrity⁸⁰, this present paper is a *post-hoc*, in-depth analysis of our U.S. Medicine’s obfuscation during our American COVID-19 epidemic from 2020 to the present diminishing foundational tenets in the treatment of Infectious Diseases perpetuated as ongoing misdirections throughout the COVID-19 endemic therapeutic time-line *ad infinitum*. (2.1 Table 1)

METHODS:

I. Historical and Legal Preservation of Data Reported over the Last 5 years: In early June 2020, consistent with the unwritten policy⁸¹ of Dr. Anthony Fauci, M.D., Director, National Institute for Allergy and Infectious Diseases (NIAID), that:

PS. I forgot to say there is no worry about FOIAs. I can either send stuff to Tony on his private gmail, or hand it to him at work or at his home. He is too smart to let colleagues send him stuff that could cause trouble.

Dr. Fauci requested, Kara Harris, MPH⁸², Section Chief for Controlled Correspondence and Public Inquiries, Legislative Affairs and Correspondence Management Branch, Office of Communications and Government Relations, NIAID, U.S. National Institutes of Health (NIH) of the U.S. Public Health Service to respond to my communication with his office. (**Attachment IV**) Thus, Ms. Harris thanked me for my communication⁸² to Dr. Fauci entitled: **Time: The Crucial Independent Variable of the COVID-19 Pandemic.**⁸⁴ This seemingly innocuous thank-you letter from Ms. Harris labelled my submission (and all future submissions) as NIAID Case file # 12276. On August 30, 2021, 14 months after the establishment of NIAID case file #12276 in a phone conversation⁸⁵ from “Meg” of Ms. Harris’s NIAID office, NIAID case file #12276 was confirmed to still exist. This confirmation phone call to my St. Louis VAMC office phone from Ms. Harris’ office was in response to my call to Ms. Harris’ office earlier that morning regarding Dr. Fauci’s presentation on Antibody treatment and Vaccine prophylaxis of COVID-19 from *The White House* of August 24, 2021, <https://www.youtube.com/watch?v=AZNP05w2cxU> (10:22 to 15:27 minutes in the youtube presentation).⁸⁶ The NIAID case file #12276 label validated the legally mandated preservation by the NIAID of all communications that was then and would be in the future submitted by me to the NIAID with the label of #12276. Thus, over the last five years, I have also included in NIAID Case file #12276 submissions to the U.S. Department of Veterans Affairs (VA), the U.S. National Institutes of Health (NIH), the U.S. Food & Drug Administration (FDA), the Centers for Diseases Control (CDC), *The White House*, etc. Some of these submissions to NIAID case file #12276 are outlined in **Attachment II**; a more inclusive, comprehensive accumulation of **Attachment II** has been uploaded to the *Internet Archive*^{84,85, 87-94}; and all are protected within the NIAID and are legally discoverable under the Freedom of Information Act, 5 U.S.C. 552.⁹⁵ Consistent with federal law, 5 U.S.C. 552⁹⁵, all documents submitted to NIAID case file #12276 should be preserved, archived by the NIAID and legally discoverable “pursuant to the nine exemptions and three exclusions” listed in 5 U.S.C. 552⁹⁵ for a nominal fee set by the U.S. Government through a formal request of the Freedom of Information Act (FOIA) officer of the NIAID^{96,97}, NIH of the U.S. Department of Health and Human Services (DHHS). Within these submissions (posted for no personal financial gain on my part), is an annotated, chronological outline of references (abridged by the enormity of the World’s documentation) regarding the background and the fight of the COVID-19 epidemic throughout U.S. Medicine and the United States public arena.^{85,93} While much of the background information for this paper can be accessed through the Freedom of Information Act process, (1) a manuscript of this present completed article will be submitted in the future to the *New England Journal of Medicine* (NEJM)⁹⁸ for publication to specifically counter the paltering NEJM article: *Early Convalescent*

Plasma for High-Risk Outpatients with Covid-19 (and its supplement)^{99,100}; (2) will also be submitted to the NIAID case #12276 file for historical preservation and availability to all wishing to request it and read it through the formal process under the Freedom of Information Act, 5 U.S.C. 552⁹⁵⁻⁹⁷; and to other Federal agencies, companies, individuals, etc. for whom this article will be instructive. I see this as my personal ethical duty to reconcile and correct the misinformation submitted to history to the veteran patients for whom I served for over a quarter of a century under the auspices of the Veterans Health Administration (VHA), the people of America, and to humanity for all time as I am a physician and surgeon, former Professor of Surgery, and former Federal physician.

II. The rationale and methods of addressing Electronic Overwriting:

- A. Data bases and source material used in the preparation of this paper: **Attachment VIII)**
- B. The analysis of public information obscured by electronic overwriting and URL changes **See that which follows in this Section II and subsequent Section III**
- C. Avoiding the misinformation of obfuscating, lies of omission, and paltering: In the development of this analysis, an extensive collection of source materials from Medical publications, Federal and International data bases, and other media were reviewed, correlated, and filed. **(Attachments II and III)** In dealing with Federal documents of the VA, the NIH, the FDA, etc. fact checking of previous earlier versions of a document was many times difficult, if not impossible, if the URL of the previous or original document had been changed and/or the previous versions had been electronically overwritten. If the URL of the document was known and the *Internet Archive*⁸⁷⁻⁸⁹ had sometime in the last quarter of a century digitized the document, then using the *Wayback Machine*⁸⁹ **(the search engine of the Internet Archive)** and the present URL, previous captured versions of the document with the same URL could be located to scrutinize what had been electronically overwritten.

While there are many official policies and protocols positively detailing the methodology of electronic overwriting for secure data destruction¹⁰¹⁻¹⁰², such an extensive electronic overwriting process destroys the previous unique-specifics of the documentation and terminates the electronic paper-trail of document evolution. **This subliminal, ubiquitous methodology is utilized extensively by many in the Executive Branch of the U.S. Government at the present time. In the preparation of this present analysis, electronic overwriting pervasively terminated the chronological history of a document's existence and was extremely detrimental to the development of this present analysis.** Within the Executive Branch of the Federal Government, this pervasive, overutilized, abusive *status quo* process of electronic overwriting destroys the document's paper-trail of the previous history which clearly violates the foundational intent of the Sarbanes-Oxley Act of 2002, 18 U.S.C. §1512(c)(1).¹⁰³ Such electronic misdirection or outright destruction of information—I would allege—is a flagrant criminal violation of U.S. law as was confirmed recently in the opening sentence of *Fischer v. United States*^{104,105} by the Supreme Court of the United States on June 28, 2024:

The Sarbanes-Oxley Act of 2002 imposes criminal liability on anyone who corruptly “alters, destroys, mutilates, or conceals a record, document, or other object, or attempts to do so, with the intent to impair the object’s integrity or availability for use in an official proceeding.” 18 U.S.C. §1512(c)(1).

This pervasive process of electronic overwriting permeates the Executive Branch of the Federal Government at present time which I would allege is a blatant violation of 36 CFR § 1222.26.¹⁰⁶ For example, in the VA’s Veterans Health Administration (VHA), there is a > 64-page document entitled Directive 6300(1), RECORDS MANAGEMENT¹⁰⁷, dated October 22, 2018—which ironically is overwritten with a red stamp of the transmittal sheet: **AMENDED September 22, 2020** making the previous official document of October 22, 2018 non-discoverable even with the Wayback Machine as its URL is uploaded to one’s computer as an individualized .pdf file. VHA Directive 6300(1) specifically outlines the process, organization, preservation, and archiving of all records in the VHA to be consistent with the National Archives directive¹⁰⁸: Universal Electronic Records Management (ERM) Requirements (<https://www.archives.gov/records-mgmt/policy/universalermsrequirements#:~:text=The%20Universal%20ERM%20Requirements%20identify,use%20when%20developing%20system%20requirements>). No where is the word “overwriting” ever mentioned, permitted, or proscribed; but there are admonishments for maintaining documents, promoting access, and a prohibition against deletion of records and documentation:

What are the general recordkeeping requirements for agencies?

- (a) To ensure the adequate and proper documentation of agency programs, each program must develop recordkeeping requirements that identify:
 - (1) The record series and systems that must be created and maintained to document program policies, procedures, functions, activities, and transactions;
 - (2) The office responsible for maintaining the record copies of those series and systems, and the applicable system administrator responsible for ensuring authenticity, protection, and ready retrieval of electronic records;
 - (3) Related records series and systems;
 - (4) The relationship between paper and electronic files in the same series; and
 - (5) Policies, procedures, and strategies for ensuring that records are retained long enough to meet programmatic, administrative, fiscal, legal, and historical needs as authorized in a NARA-approved disposition schedule.
- (b) Agencies must capture, manage, and preserve electronic records with appropriate metadata and must be able to access and retrieve electronic records, including electronic messages, through electronic searches.

36 CFR 1222.26

One blatant example of a violation of intent of 36 CFR 1222.26 within the VHA is the past eleven-year history of VHA Directive 1063, UTILIZATION OF PHYSICIAN ASSISTANTS (PA), December 24, 2013.¹⁰⁹ The initial URL document **declared the VHA preemptive over all State Medical Boards** based on the Constitution of the United States of America. Consistent with the fact that there does not exist any nationwide physician assistant (PA) licensing board (there are no nationwide physician nor national nursing licensing boards), all state medical boards credential all physician assistants (PAs) explicitly mandating that all PAs are working under a scope of practice of a licensed physician and are not independent practitioners which was controverted in the original version of VHA Directive 1063 of December 24, 2013¹⁰⁹:

2. BACKGROUND: ...

c. Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts.

Today, when direct access is attempted employing the original URL of VHA Directive 1063 of December 24, 2013¹¹⁰: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958, one is electronically diverted to a download on one's computer only that is a .pdf file stamped AMENDED June 24, 2024: i.e., [file:///Users/andrusmd1/Downloads/1063\(2\)_D_2013-12-24%20\(21\).pdf](file:///Users/andrusmd1/Downloads/1063(2)_D_2013-12-24%20(21).pdf) thus preventing the access of the original version of VHA Directive 1063 of December 24, 2013.¹⁰⁹

On August 14, 2014, an electronic copy of VHA Directive 1063 was initially captured by the *Internet Archive* of the original version of December 24, 2013--8 months after VHA Directive 1063 was originally published (uploaded to the *Internet*)¹⁰⁹:
https://web.archive.org/web/20140814150238/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

The May 17, 2022 version of VHA Directive 1063 which rescinded the misinterpretation / misapplication of the Supremacy Clause of the U.S. Constitution was captured by the *Internet Archive* on August 12, 2022, which was 3 months after the publication of the overwritten "AMENDED" VHA Directive 1063 of May 17, 2022 version and nine years and eight months from the publication of the original version of VHA Directive 1063¹¹¹:
https://web.archive.org/web/20220812082647/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

The latest version of June 18, 2024, was captured by the *Internet Archive* on July 18, 2024, which was one month after the publication in the June 18, 2024 version and eleven years and seven months from the publication of the original version of VHA Directive 1063 which contained the misinterpretation / misapplication of the Supremacy Clause of the U.S. Constitution.¹¹⁰
https://web.archive.org/web/20240718213316/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

Besides perpetuating electronic overwriting of a previous misinterpretation/misapplication of a foundational statement of the U.S. Constitution, the adjustments to this document over the last 11 years are clear violations of the Sarbanes-Oxley Act of 2002¹⁰³ and also violated the VHA and the U.S. National Archives directives for amending and preserving the historical paper trail. Both "AMENDED" versions of May 17, 2022, and June 18, 2024, retained in all three versions of VHA Directive 1063 Transmittal Sheets the responsible, "signatory" party for VHA Directive 1063 as listed: VHA Under Secretary for Health, Robert A. Petzel, M.D. Dr. Petzel resigned "under fire" over the Phoenix, Arizona VA scandal, in May 2014—six months after the original VHA Directive 1063 was signed officially by himself.¹¹²⁻¹¹³ Eight and ten years respectively, the "AMENDED" VHA Directives 1063 versions have covered-up the misinterpretation / misapplication (which violates States rights) of the Federal Government Supremacy Clause under the U.S. Constitution of the United States of America,

Please note, the VHA Under Secretary for Health, is the highest ranking Medical Officer in the U.S. Department of Veterans Affairs and leads the Veterans Health Administration (VHA). The VHA Under Secretary for Health oversees the 172 VA Medical Centers, >1300 CBOCs, and the VHA's part of the U.S. Department of Veteran Affairs' VA annual budget of over \$300 billion.¹¹⁴ Dr. Petzel^{92,112-118}, along with the other four of us, Andrus^{37,83-85,90,92-94,140,249}, Bowen⁹², Garthwaite^{92,119}, and Roswell^{92,120,121}, was interviewed for the VHA Under Secretary for Health on December 10, 1999, by the VHA USH Commission with three of the individuals: Drs. Garthwaite, Petzel, and Roswell being subsequently referred for vetting to *The White House* in early 2000. Although at that specific moment in history, Dr. Garthwaite's name was submitted to the Senate and he was confirmed in the Spring of 2000, Garthwaite (2000 – 2002), Roswell (2002-2004), and Petzel (2010-2014) would serve as VHA Under Secretaries for Health.

Thus, using the *Internet Archive's Wayback Machine*^{88,89} became the one most important fact-checking methodology employed extensively in the development of this paper providing a “following of the paper-trail” back to the origins of the documents regarding fundamental issues of the DHHS, the FDA, the NIH, the NIAID, the VHA, etc.

III. Fact checking and identifying misstatements, misinterpretations, and misrepresentations of official definitions result in *paltering* defilements, violations of Federal law, and lies of commission and omission (Attachments: III, VI, and VIII, References of Attachments I-VIII). As with electronic overwriting and URL obliteration, obfuscation of definitions is ethically wrong and led frequently to inappropriate or fallacious analyses, spurious conclusions, and incorrect policies and directives in U.S. Medicine’s addressing of the America’s COVID-19 epidemic. Ferreting out and defusing euphemisms¹⁵ became another keystone, focused methodology of this research:

The comedian George Carlin grounded his professional career in his satirizing our country’s fixation on euphemisms.¹⁵ In American society today, we seemingly have become unwittingly partners and victims to our willingness to euphemistically diminish our assessments to mediocrity--all too often, relegating the rejection of advancements of foundational concepts in Medicine to that of *Chronic Denial*. (Attachment V)¹²²⁻¹²⁴ Throughout our society today, we have become comfortable with incorrectly expressing and flippantly misusing the definitions and meanings of words and phrases; ignoring essentials to the point of violating the intent of the rules of science, nature, and the laws of our country in our daily lives; lying sometimes by commission but, most of the time, by omission and paltering; and championing *ad nauseam* the *ad hominem* attacks levelled against our fellow man as a standard methodology of bravado and self-assertiveness to discard the worth of our fellowman. During the COVID-19 epidemic, we, as individuals, in the United States of America through our institutions like that of Academic Medicine, Medical Publications, the U.S. Federal Government, etc. have distorted foundational concepts in Medicine which have resulted in disastrous outcomes for individuals, families, and communities throughout our country which were concomitant with >1,000,000 deaths associated with the American COVID-19 epidemic.

Much of our short-comings during the United States COVID-19 epidemic were ambiguous definitions, misinterpretation of definitions, and resultant obfuscations (*Palterings*) due to:

1. our naïve, pervasive utilization of euphemisms and manipulation of definitions
2. employment of electronic overwriting of policies, directives, and other documents with resultant subliminal electronic destruction of previous versions;
3. disregard for human rights by *de facto* suspension of EMTALA and desuetude of the Right to Try Act, etc.;
4. disregard for and misapplications of standardized definitions and policies of the FDA, the NIH, the CDC, the VA, and Medicine-in-general;
5. emphasis on our country’s obsession that money can buy the right thing in Medicine which is far-from-the-truth;
6. disregard and daily misapplication to the truism that “...You cannot legislate for virtue”; and
7. unrestrained lies of commission and omission that indirectly resulted in greater than 1,000,000 deaths associated with these individuals’ contraction of the coronavirus, SARS-CoV-2, (COVID-19).

Most importantly in the methodology of addressing of definition ambiguity, misinterpretation, misapplication, and paltering, the first part of the Results portion of this paper is a succinct outline: Table 1: Digital vs. Analog—Yes, No, Maybe in Medicine and Treatment of Covid-19. Table 1 is probably the most of important foundational methodology within this paper in the analyzing of branchpoint definitions with regards to the misapplications of definitions within Medicine, Medical Statistics^{Attachment VI}, and the Legal Mandates^{2.2 Definition_Fundamentals_Legal_Mandates background} involving specifically the U.S.A.'s response to the coronavirus, SARS-CoV-2, COVID-19. In **Table 1**^{2.1 Table 1- Digital vs. Analog-Yes, No, Maybe in Medicine and Treatment of Covid-19}, there is a categorizing of branchpoints as Positive, Relative, and Negative. In Medicine, as in life, there is only one absolute branch point: **Lived** versus **Died**. In our present computerized mindset of a “binary look” at the World today, we have mistakenly equated all decisions to Yes versus No equating the digitalization of 1 versus 0, e.g.: Lived versus Died, etc. The World and Medicine overwhelmingly are of the Relative or Analog –not just Yes/No. **Table 1** is a hierarchical analysis that was then employed in the development of the **Results, Discussion, and Recommendations** portions of this paper. This analysis is based on the communications from April 5, 2020, going forward from Dr. Andrus to the National Institute for Allergy and Infectious Diseases (NIAID), Case file #12276; the FDA; the VA; *The White House*, etc. and the summary publication: Andrus CH: *Dear Mr. President: COVID-19 and Where We Went Wrong* of February 2, 2023, uploaded to the *Internet Archive* on 2023-09-12 <https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02> ^{37, 83-85,90,92,93}

IV. Pathophysiology, Statistics, Legal Abridgments: Some of the aberrancies in our applications of foundational principles and tenets of Medicine and, I allege, the violations of legal mandates throughout the last five years resulted from the repeated euphemistic manipulations of definitions¹⁵, electronic overwriting, destruction-of-access-to-a-logical-pathway by changing electronically the ULS addresses, etc.^{Attachments VIII} Some of the analyses have been incorporated into the **Discussion** section of this paper and referenced to provide the reader the opportunity to explore these inconsistencies in more depth.

Unfortunately, all this information has been tainted with the euphemistic manipulation of definitions, the mistaken emphasis on self-serving theories, and the deemphasis of the clarity and importance of the pathophysiology of the disease cause by coronavirus, SARS-CoV-2, COVID-19. **The resultant logic of direct treatment (not prophylaxis) based on the clinical expression of the pathophysiology of COVID-19 with immunotherapy, antivirals, etc. has been dismissed for all intensive purposes by the NIH and FDA.** Thus, the most important essence of this present paper's methodology is to provide the reader with reference foundational terminology and applications to organize pertinent facts from self-serving fiction. **Attachment III: Reductio ad Absurdum: The COVID-19 Tale of Two Presidents, the Ramifications of Fifty Years of American Scandal, Therapeutic Nihilism, and Medical Stupidity**^{0.4 Attachment III} *Reductio ad Absurdum* is the face sheet of a 100-page document (between pages e31 to e130) summarizing that which was submitted to President Biden over the course of his term-in-office.^{94,123} The complete 848 page summary of submissions to the FDA, the NIAID, the VA, and *The White House* under NIAID case file #12276 was uploaded to the *Internet Archive*

entitled: **Book 4: President Biden's July 7, 2023 Response Letter to Dr. Andrus' submission of 2023-04-27 update 11-7-23.pdf**⁹³ :

Book 4: President Biden's July 7, 2023 Response Letter to Dr. Andrus' submission of 2023-04-27 update 11-7-23.pdf Internet Archive, Uploaded 2024 Feb 05, <https://archive.org/details/book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong/> , [Only 382 pages sometimes can be accessed, thus it was again uploaded on March 5, 2024, to the Internet Archive as Title: **0.4 Book 4 Biden response to the Summary of Book 1 COVID 19 And Where We Went Wrong 2nd Attemp** <https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attemp> *** NIH NIAID Case #12276

In the following Results section, the treatment with immunoglobulins of a viral infection with immunoglobulins and an outline of pertinent definitions in Table 1^{2.1} Table 1 Digital v. Analog—Yes, No, Maybe in Medicine and Treatment of Covid-19 are discussed. Then, using comparison statistics, e.g.: 2x2 contingency tables, a series of Chi Square analyses are correctly applied to contradict the invalid impression expressed throughout the literature regarding the efficacy of COVID-19 Convalescent Plasma and implemented by U.S. Medicine. 2x2 contingency tables of the FDA's published conclusions of August and September 2020 were reconstructed from the published FDA conclusions by a series of iterative Chi Square analyses using the statistical program: GraphPad Prism 10¹²⁵ (and SAS's StatView II¹²⁶ was used throughout the five years in other analyses).

Results:

All of us, as physicians, should have the fundamental knowledge regarding early treatment (≤ 72 hours from diagnosis) of a novel virus with antivirals^{16,37,128-130,145,148-157,186,196,202-206} and synergistically^{129,196,202-204} with exogenous immunoglobulins.¹²⁷⁻¹³⁰ (An important, universal, concept of the time-dependent effect of *Passive Immunization* on the initial viremia and the later host-systemic phase applicable to COVID-19 and all viruses is depicted in the self-explanatory Figure 8.2 of Chapter 8: *Passive Immunization* by Slifka MK, Amanna IJ: Chapter 8: Passive Immunization. Plotkin's Vaccines 7th Ed, 2018: p 8,epage 6.³⁴) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7151993/pdf/main.pdf>. **During the COVID-19 Pandemic, through the truly altruistic, selfless disclaimer of the publisher, ELSEVIER, Figure 8.2 that follows was made available to the World (and unfortunately, we did not pay attention and emphasize Figure 8.2's importance):**

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

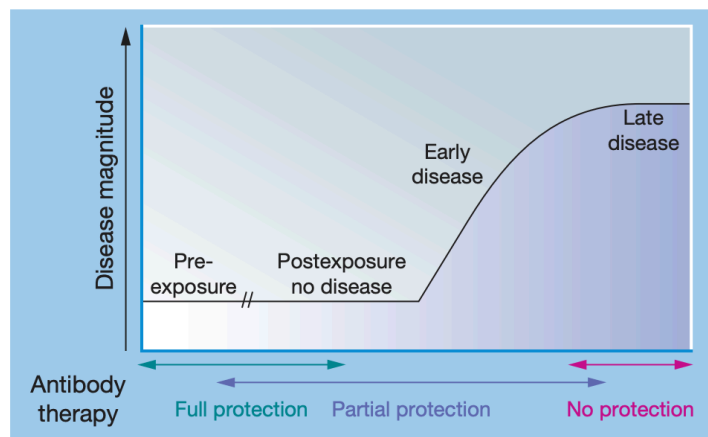


Figure 8.2. Efficacy of passive immunity decreases with disease progression. Full protection from symptomatic disease is best achieved through prophylactic administration of antibody therapy prior to exposure or infection. However, antibody therapy may also be highly effective at early points postexposure, prior to the onset of disease symptoms. Passive immunity is generally less effective when administered after the onset of symptomatic disease, and typically shows little to no clinical benefit once severe late-stage disease has occurred.

Overall, U.S. Medicine during the COVID-19 epidemic response was typified by: (1) a chronology of errors, political misinformation, and self-centered promotion and advancement;

(2) disregard for some foundational concepts of medicine in the treatment (not prophylaxis) of viruses; and (3) a morass of self-serving ignorance, arrogance, and stupidity contributory to our minimizing the importance for the immediate TREATMENT with immunoglobulins and antivirals of **ALL INFECTED INDIVIDUALS** early in the course (<72-96 hours from diagnosis) of their individually-contracted disease which have been foundational pillars of therapeutics for novel viruses throughout the twentieth century. While we officially hailed **prophylaxis** (Active Immunization/Vaccines) as the foremost management methodology during the American COVID-19 epidemic of the World-wide pandemic, we, as U.S. Medicine, **FAILED to treat immediately (within 72-96 hours of diagnosis) all those infected** with the novel virus: coronavirus, SARS-CoV-2, COVID-19 with immunoglobulins and antivirals!

On March 2, 2021, this misdirected obfuscative paltering in U.S. Medicine culminated in the FDA rejecting immediate treatment with COVID-19 Convalescent Plasma (CCP) presenting to emergency departments.¹³¹ This resulted in a nationwide restriction in use or complete discontinuation of blood bank collections, processing, and distribution of COVID-19 Convalescent Plasma.¹³²⁻¹³⁴ The *ex post facto* publication of the results of the NIH funded SIREN-C3PO trial¹³¹⁻¹³⁸ in a November 2021 article in the *New England Journal of Medicine*^{99,100}: (1) violated the basic tenets of medical statistics, our ethical responsibility to educate truthfully, and our human sensibilities and responsibilities of equitable, compassionate care towards all our fellow Americans:

Korley FK, Durkalski-Mauldin V, Yeatts SD, Schulman K, Davenport RD, Dumont LJ, El Kassab N, Foster LD, Hah JM, Jaiswal S, Kaplan A, Lowell E, McDyer JF, Quinn J, Triulzi DJ, Van Huysen C, Stevenson VLW, Yadav K, Jones CW, Kea B, Burnett A, Reynolds JC, Greineder CF, Haas NL, Beiser DG, Silbergleit R, Barsan W, and Callaway CW for the SIREN-CEPO Investigators: **Early convalescent plasma for high-risk outpatients with Covid-19.** N Engl J Med 2021 November 18; 385 (21): 1951-1960.
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103784>⁹⁹

Korley FK, Durkalski-Mauldin V, Yeatts SD, *et.al.*: **SUPPLEMENTARY MATERIAL to Early convalescent plasma for high-risk outpatients with Covid-19.** N Engl J Med 2021 November 18; 385 (21): 1951-1960 can be found online at the bottom of the page of the online version of this article:
<https://www.nejm.org/doi/full/10.1056/NEJMoa2103784#ap0>¹⁰⁰

and (2) this NEJM article inappropriately and disingenuously validated the NIH funded SIREN-C3PO Randomized Controlled Trial (RCT) trial as an appropriate multi-institutional RCT.¹³⁵ If the SIREN-C3PO RCT protocol was reviewed reasonably by any non-proprietary University-based IRB, it would have been rejected as extremely underpowered.^{99,139,140}

In March 2021, in acting upon the unpublished “results” of the SIREN-C3PO Clinical trial.gov NCT04355767¹³¹, that later would be published in the *New England Journal of Medicine* (NEJM), November 18, 2021: Early Convalescent Plasma for High-Risk Outpatients with Covid-19^{99,100}, the NIH, the FDA, and U.S. Medicine in general was misled into condoning the driving of the *final nail-in-the-coffin* to the appropriate use of **Passive Immunization** for **ALL** in an organized, systematic administration early (<72 – 96 hours from diagnosis) during the course of the disease. In the Spring and Summer of 2021, the American blood banks¹³²⁻¹³⁴ acted upon the unpublished SIREN-C3PO clinical trial even though the actual “results” were not presented / published to U.S. Medicine and the American public until 8 months later.⁹⁹⁻¹⁰⁰ Thus, *The New England Journal of Medicine* permitted publication of the article epitomizing a travesty of lying

with statistics entitled: Early Convalescent Plasma for High-Risk Outpatients with Covid-19⁹⁹: <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103784> and its Supplement Appendix¹⁰⁰ accessible only through the NEJM's on-line URL site: https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl_file/nejmoa2103784_appendix.pdf through clicking are the box at the end of the website leading to the URL: <https://www.nejm.org/doi/full/10.1056/NEJMoa2103784> . In so doing, the NEJM abandoned its promise to humanity to uphold the tenets that the NEJM professes to the World as it is a signatory and has ongoing participating committee members to the International Committee of Medical Journal Editors (ICMJE). The NEJM has failed to live up to that which it boasts: "The most trusted, influential source of new medical knowledge and clinical best practices in the world"^{75-80,141-143}.

Integrity Safeguards⁸⁰

The *New England Journal of Medicine (NEJM)* is committed to publishing the highest quality research and reliable, authoritative review articles. No NEJM editor is permitted to have any financial relationship with any biomedical company. NEJM strives to identify, vet, and publish research that will make a difference in medicine. The mainstays of credibility are:

- Editorial independence
- Academic rigor in editing and reviewing research

NEJM has taken a notable leadership role over the past decade and a half in advocating for stronger, more consistent standards of integrity across the entire medical publishing industry. For example, NEJM:

- Played a significant role in the 2005 campaign to require clinical trial registration.
- Since 1984, has requested author disclosures, and pioneered in 2009 with the International Committee of Medical Journal Editors (ICMJE), a universal disclosure form that requests that authors report all relevant financial conflicts during the 36 months before publication.
- Took the lead among medical journals in 2011 to publish study protocols with all randomized, controlled trials. NEJM is still one of the few general medical journals that publishes protocols with all randomized trials.
- Broke new ground, along with the ICMJE, in requiring sharing of clinical trial data. As of 2018, NEJM required authors to include a data sharing statement when submitting an article for publication. In 2019, they were required to enter a data sharing plan in the trial's registration.

Beyond promoting clinical trial registration and ICMJE universal standard disclosure for all scientific medical reporting, NEJM:

- Works diligently to ensure that research conclusions are neither overstated nor misleading, that results are placed in proper context for clinical practice, and that peer review editorial informs editorial decision.
- Grants immediate free access to low-income countries through partnership with Reasrch4Life's Access to Research in Health (Hinari) program.
- Enforces strict rule around disclosure of paper authorship.
- Carefully reviews manuscript, protocol, and trial registrations of every randomized clinical trial.
- Maintains strict separation between editorial and business considerations.

Early Convalescent Plasma for High-Risk Outpatients with Covid-19 palteristically concluded in its abstract's conclusion:

The administration of Covid-19 convalescent plasma to high-risk outpatients within 1 week after the onset of symptoms of Covid-19 did not prevent disease progression. (SIREN-C3PO ClinTrials.gov number, NCT04355767).⁹⁹

Contrary to the above statement, a 2x2 contingency table and Chi-square analysis using GraphPad Prism 10 for MacOS¹²⁵ of the hierarchal figure on page 1955 of the November 18, 2021, NEJM article⁹⁹, entitled: Figure 1. Enrollment, Randomization, and Analysis Populations., yields an outcome that is not (statistically) significant: **Table 2: Chi-square analysis of Figure 1 of NEJM article, November 18, 2021:**

Contingency	NEJM Paper Figure 1		
Table Analyzed	Data 1		
P value and statistical significance	Fisher's exact test		
Test	0.1224		
P value summary	ns		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	No		
Data analyzed	Lived	Died	Total
CCP	243	5	248
Placebo	248	1	249
Total	491	6	497
Percentage of row total	Lived	Died	
CCP	97.98%	2.02%	
Placebo	99.60%	0.40%	
Percentage of column total	Lived	Died	
CCP	49.49%	83.33%	
Placebo	50.51%	16.67%	
Percentage of grand total	Lived	Died	
CCP	48.89%	1.01%	
Placebo	49.90%	0.20%	

In fact, while there were five deaths in the CCP group (experimental group) and only 1 in the control (placebo) group, these were not (statistically) significant. The real reason these results for “death” were not significant is that these reported SIREN-C3PO results made the assumption that this subgroup of 497 patients only: CCP: 243 lived v 5 died versus the placebo control of 248 lived v 1 died, **was representative** of the all-inclusive U.S. population presenting to ERs with COVID-19 symptomatology equal to or over the age of 50 years—WHICH IS NOT VALID. This study was markedly, inherently skewed as non-representative of the proposed-to-be-studied U.S. population from the onset due to a multitude of factors of which the most prominent is that the study reported an exclusion of 3479 of 3990 (87.2%) from inclusion group in the randomization process. This initial assessment of the eligibility process was markedly not representative of the U.S. population acutely infected with coronavirus, SARS-CoV-2, COVID-19, as was purported to be the essence of the Methods section of the Abstract of Early Convalescent Plasma for High-Risk Outpatients with Covid-19⁹⁹:

METHODS

In this randomized, multicenter, single-blind trial, we assigned patients who were being treated in an emergency department for Covid-19 symptoms to receive either one unit of convalescent plasma with a high titer of antibodies against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or placebo. All the patients were either 50 years of age or older or had one or more risk factors for disease progression. In addition, all the patients presented to the emergency department within 7 days after symptom onset and were in stable condition for outpatient management. The primary outcome was disease progression within 15 days after randomization, which was a composite of hospital admission for any reason, seeking emergency or urgent care, or death without hospitalization. Secondary outcomes included the worst severity of illness on a 8-category ordinal scale, hospital-free days within 30 days after randomization, and death from any cause.

Thus, most-importantly, the primary, subliminal null hypothesis (H_0) was not supported in the underlying intent, process, and publication of the paper: The mortality outcome of those included versus those excluded must be consistent with the historical population matched controls (Graphs IV above):

Table 3: Chi-square Analysis using GraphPad Prism 10 of NEJM Article's Non-Representation of the U.S. Population by Age-adjusted Mortality

Contingency	Chi-square Included v Excluded-	Lived v Died for ≥ 50 yr old	
Table Analyzed	Data 1		
P value and statistical significance			
Test	Fisher's exact test		
P value	<0.0001		
P value summary	****		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	Yes		
Data analyzed	Lived	Died	Total
Included	491	6	497
Excluded	3041	452	3493
Total	3532	458	3990
Percentage of row total	Lived	Died	
Included	98.79%	1.21%	
Excluded	87.06%	12.94%	
Percentage of column total	Lived	Died	
Included	13.90%	1.31%	
Excluded	86.10%	98.69%	
Percentage of grand total	Lived	Died	
Included	12.31%	0.19%	
Excluded	76.22%	11.33%	

Contingency	Chi-square Included v Excluded-	Lived v Died for mean 60 yr old	
Table Analyzed	Data 3		
P value and statistical significance			
Test	Fisher's exact test		
P value	<0.0001		
P value summary	****		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	Yes		
Data analyzed	Lived	Died	Total
Included	491	6	497
Excluded	2859	834	3293
Total	3150	840	3790
Percentage of row total	Lived	Died	
Included	98.79%	1.21%	
Excluded	80.75%	19.25%	
Percentage of column total	Lived	Died	
Included	15.59%	0.94%	
Excluded	84.41%	99.06%	
Percentage of grand total	Lived	Died	
Included	12.96%	0.16%	
Excluded	70.16%	16.73%	

Contingency	Chi-square Included v Excluded-	Lived v Died for mean 70 yr old	
Table Analyzed	Data 4		
P value and statistical significance			
Test	Fisher's exact test		
P value	<0.0001		
P value summary	****		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	Yes		
Data analyzed	Lived	Died	Total
Included	491	6	497
Excluded	2677	816	3493
Total	3168	822	3990
Percentage of row total	Lived	Died	
Included	98.79%	1.21%	
Excluded	76.64%	23.36%	
Percentage of column total	Lived	Died	
Included	15.50%	0.73%	
Excluded	84.50%	99.27%	
Percentage of grand total	Lived	Died	
Included	12.31%	0.15%	
Excluded	67.09%	20.49%	

Contingency	Chi-square Included v Excluded-	Lived v Died for mean 80 yr old	
Table Analyzed	Data 5		
P value and statistical significance			
Test	Fisher's exact test		
P value	<0.0001		
P value summary	****		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	Yes		
Data analyzed	Lived	Died	Total
Included	491	6	497
Excluded	2496	997	3493
Total	2987	1003	3990
Percentage of row total	Lived	Died	
Included	98.79%	1.21%	
Excluded	71.46%	28.54%	
Percentage of column total	Lived	Died	
Included	16.44%	0.60%	
Excluded	83.56%	99.40%	
Percentage of grand total	Lived	Died	
Included	12.31%	0.15%	
Excluded	62.56%	24.99%	

Figure 1, page 1955⁹⁹ of:

Korley FK, Durkalski-Mauldin V, Yeatts SD, Schulman K, Davenport RD, Dumont LJ, El Kassas N, Foster LD, Hah JM, Jaiswal S, Kaplan A, Lowell E, McDyer JF, Quinn J, Triulzi DJ, Van Huysen C, Stevenson VLW, Yadav K, Jones CW, Kea B, Burnett A, Reynolds JC, Greineder CF, Haas NL, Beiser DG, Silbergleit R, Barsan W, and Callaway CW for the SIREN-CEPO Investigators: **Early convalescent plasma for high-risk outpatients with Covid-19**. N Engl J Med 2021 November 18; 385 (21): 1951-1960.

<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103784>⁹⁹

(--also inclusive is the NEJM supplement:

Korley FK, Durkalski-Mauldin V, Yeatts SD, *et.al.*: **SUPPLEMENTARY MATERIAL to Early convalescent plasma for high-risk outpatients with Covid-19**. N Engl J Med 2021 November 18; 385 (21): 1951-1960 can be found online at the bottom of the page of the online version of this article:

<https://www.nejm.org/doi/full/10.1056/NEJMoa2103784#ap0>¹⁰⁰)

is a hierarchical algorithm which biased internally the SIREN-C3PO RCT by eliminating the vast majority of the patients presenting with “early” COVID-19 as the inclusion criteria was regulated to a randomization of the administration of CCP versus placebo based on an arbitrary, nebulous, individual qualitative parameter: “...high-risk outpatients with Covid-19”⁹⁹ excluding

those qualitatively designated as well-enough to be discharged without treatment or too sick requiring hospitalization, e.g.:

- a. a majority of those presenting to the Emergency Rooms in this multi-institutional RCT were excluded: **3479/3990 = 87.2% excluded**;
- b. the inexactitude of the *variable qualitative nature* of the exclusion criteria at both extremes (tails of the bell-shaped curve) of a normal population distribution curve is non-sensical skewing of the analysis and making any conclusions impossible, e.g. 1). where the patients were not sick enough for inclusion [“had no trial defined Covid-19 risk factor” (682) or “had no Covid-19 symptoms” (153) = **835 or 24.0% of those excluded**]; 2.) where the patients were too sick for inclusion [“symptoms >7 days” (955) or “were no longer intended for discharge” (271) = **1226 or 35.2% of those excluded**]; or 3.) where patient’s presentation was not convenient for the institution for inclusion in the RCT [“had ED visit outside of screening hours” (561), “were missed during the screening hours” (39), or “had site operational issue” (110) = **710 or 20.4% of those excluded**]**-- a total exclusion number due to the inexactitude of the *variable qualitative nature* of the exclusion criteriae was (835 + 1226 + 710)/ 3479 = (2771/ 3479) = 79.6% of those excluded**;
- c. inclusion of 30 of the 38 institutional sites (80%) which individually contributed a limited, insignificant number of patients to the randomization process is disingenuous at best. The distribution of contributing institutions can be found in the online Supplementary Appendix (page 2-5)¹⁰⁰ **ONLY** which defies a controlled randomization in the total trial by relegating it at the local institutional level. Within the individual contributory institutions, their numbers are statistically insignificant, e.g.: How does one randomize 1 patient between the CCP group vs. the control group in the 4 institutions that contributed only 1 patient each?— You can’t split a patient in half to randomize from one institution with only one submission!
 - i. Above 20 subjects from eight institutions (which should be statistically valid for analysis):

50,43,33,27,26,25,24,23 = **251 inclusive subjects from 8 institutions:**
 $[251/(251+246)] \times 100 = \mathbf{50.5\% \text{ subjects included in the final analysis from institutions submitting more than 20 subjects per institution}}$
 - ii. Below 20 subjects per institution (which are considered statistically insufficient per each individual participating institution) from the 38 participating institutions:
 - 18 subjects from 3 institutions (45)
 - 12 subjects from 2 institutions (24)
 - 11 subjects from 2 institutions (22)
 - 10 subjects from 2 institutions (20)
 - 9 subjects from 3 institutions (27)
 - 8 subjects from 3 institutions (24)
 - 7 subjects from 2 institutions (14)
 - 6 subjects from 3 institutions (18)

5 subjects from 1 institution (5)
 4 subjects from 6 institutions. (24)
 3 subjects from 5 institutions (15)
 2 subjects from 2 institutions. (4)
1 subject from 4 institutions (4)

246 inclusive subjects from 38 institutions submitting less than 20

subjects per institution [246/(251+246)] x 100 = 49.5%]

{Please note from Figure 1 on page 1955 of the NEJM article, the total of 497 included are consistent with the final number assigned to receive convalescent plasma ["246 were included in intention-to-treat analysis"] and ["254 were included in intention-to-treat analysis"]}

- d. corroborated the NIH's discontinuation of the SIREN-C3PO trial which led to the official disappearance of the collection, processing, and distribution by the United States blood banks of CCP in the spring of 2021 for early treatment of individuals acutely infected with COVID-19 with COVID-19 Convalescent Plasma¹³¹⁻¹³⁴;
- e. and legitimated before the American public greater than 384,000 deaths involving COVID-19 in 2020 (prior to the vaccines) of unvaccinated / immune naïve individuals in which the vast majority could have been treated within 72-96 hours of diagnosis with immunoglobulin therapy (CCP or monoclonal antibodies) and the antiviral remdesivir¹⁴⁸⁻¹⁵⁷ which was *de facto* tantamount to the DENIAL of their individual patient rights guaranteed under EMTALA¹⁵⁸⁻¹⁶¹ and/or the Right to Try Act of 2018.¹⁶²⁻¹⁶⁵

Throughout the RESULTS and DISCUSSIONS of this paper, it will be demonstrated that the FDA calculations and presentations¹⁶⁶⁻¹⁶⁷ before the American people in August and September 2020, correctly and positively confirmed COVID-19 Convalescent Plasma's safety and efficacy using the outcomes data of the Mayo Clinic / FDA Expand Access (Compassionate Use) Protocol (EAP) under the direction of the Principal Investigator, Michael Joyner, M.D., Ph.D.¹⁶⁸⁻¹⁸⁰ Despite the fact that "from April 3 to August 23, 2020, 105,717 hospitalized patients with severe or life-threatening COVID-19¹⁷⁸ were enrolled in the EAP"^{181,182}, it was consistently demonstrated (1) that there was safety in the administration of CCP and (2) there was a survival advantage if the CCP was administered to COVID-19 infected individuals within the first 72 hours after diagnosis with high titer CCP. **Prior to the blood banks¹³²⁻¹³⁴ in America in the Spring 2021 discontinuing collection of COVID-19 Convalescent Plasma (CCP) for processing, distribution, and administration and thus *de facto* bureaucratically discontinuing general availability within the United States going forward *ad infinitum*, the FDA in February 2021, correctly concluded that there is a survival advantage with CCP treatment--early after diagnosis--of high-dose CCP versus withholding CCP for all non-vaccinated and/or COVID-19-immune-naïve acutely COVID-19-infected individuals:**^{181,182}

Recommendation: The conditions of Emergency Use Authorization for CCP for the treatment of hospitalized patients with COVID-19 should be revised to exclude the use of low titer CCP. High titer CCP continues to meet criteria for Emergency Use Authorization for the treatment hospitalized patients with COVID-19 early in the course of hospitalization. The letter of authorization and accompanying fact sheets should be revised to emphasize early administration of CCP in the absence of immunodeficiency or immunosuppression. Additional results from adequate and well-controlled trials will continue to be

evaluated to further characterize the patient populations and product characteristics meeting EUA criteria.
(2| Page)

The FDA announcement¹⁶⁶ of August 23rd 2020, based on the Mayo /FDA Clinic CCP protocol, presented in a Presidential news conference¹⁶⁴ on the eve of the Republican National Convention **failed**: (1) to define the attributes and positive outcomes of COVID-19 Convalescent Plasma (CCP) to the scientific community and the American public, (2) *de facto* interrupted the availability of CCP through the Mayo Clinic / FDA Convalescent Plasma Protocol (Mayo/FDA) by compelling the discontinuation of the Mayo/FDA protocol, and (3) was dismissed by the scientific community. Former FDA Commissioner, Stephen Hahn, M.D., has been blamed¹⁸³ probably unfairly, regarding this debacle:

The push to get a vaccine approved before the election on November 3 grew stronger and stronger. The FDA commissioner, Stephen Hahn, an oncologist from MD Anderson Cancer Center in Houston, Texas, had made some missteps early in his tenure. Given the White House push for hydroxychloroquine, he had agreed to its emergency authorization, which ultimately back. Next, in a press conference about the efficacy of convalescent serum he got the percent of improvement wrong, later apologizing for mistakenly exaggerating the data. After these incidents, he made it clear to the Trump administration that in terms of vaccine authorization he and his agency would not be pressured into taking scientifically incorrect action; that vaccine approvals would not be rushed just because the White House hoped that they would be approved before the election. Rather, the FDA would follow all proper procedures to make sure they were safe and effective. Steve and the FDA did their jobs well regarding decisions about the COVID vaccines.

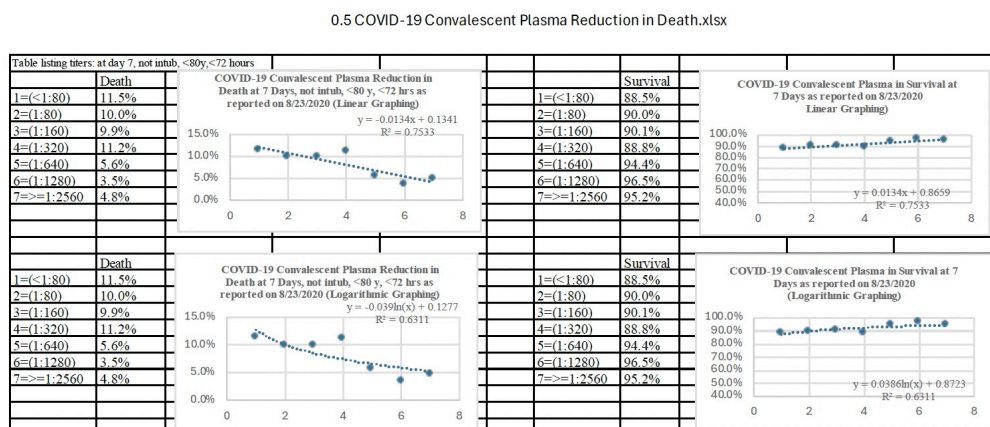
Even though the reported results on that day are a gross averaging of the mortality and the prevention of mortality (survival) by the administration of exogenous immunoglobulin (CCP), both in the reporting of mortality vs titers¹⁶⁶ (Graphs I) and in the reporting of mortality vs. ID50 (concentration of neutralizing antibodies), at the 7th day (Graphs II) and the 28th day (Graphs III) a month later before Congress on September 23, 2020¹⁶⁷, it can be graphically documented appropriately that the logarithmic plot of SURVIVAL (like a Michaelson-Menten plot^{184,185}) was significantly (statistically) increasing with increasing neutralizing antibody titers (ID50) in individuals that were treated in less than 72 hours during the viremic phase of Covid-19¹⁸⁶ (both all individuals and below age 80 years) from the initial diagnosis with COVID-19 convalescent plasma. The survival results when plotted in a logarithmic fashion of percentage survival as Michaelson-Menten graphs that follow demonstrated increasing survival approaching an asymptotic maximum survival in the early-treated patients (≤ 72 hours) when treated within the viremic phase¹⁸⁶ of the disease with increasing titers / ID50 concentrations of COVID-19 Convalescent Plasma.

By decade, the increased rate of mortality (increasing $\sim 0.5\%$ per-year-of-age over 49) calculated and graphed from mortality data publicized by the CDC¹⁸⁷ over the initial 17-months when the majority of deaths were in unvaccinated patients immunologically naïve to COVID-19 *against* increasing age (Graph IV) was consistently increasing with the coefficient of determination of the least-squared graphing, Graph IV, figure 2, calculated to be $r^2 = 0.9916$ for those greater than 49 years of age. Thus, Graph IV denote that all randomized controlled trials (RCT) performed during the American COVID-19 epidemic were **UNPOWERED** being spread over multiple decades of life with an increasing mortality of $\sim 0.5\%$ per-year-of age over 49. The results announced by the FDA on August 23, 2020¹⁶⁶, are thus muted due to inclusion of multiple decades but were still **CORRECTLY** reported by the FDA as a significant outcome ($p < 0.03$) in the ≤ 72 hour, non-intubated, ≤ 80 yr group when a 2x2 Chi-square analysis was performed and

confirmed by this analysis (Graphs I) , i.e.: *CCP High dose* v. *CCP Low dose* crossed with *alive* v. *dead* at 7 days. It is extremely important to understand that in the FDA's analysis there were three critical clinical variables subliminally influencing the FDA's reports:

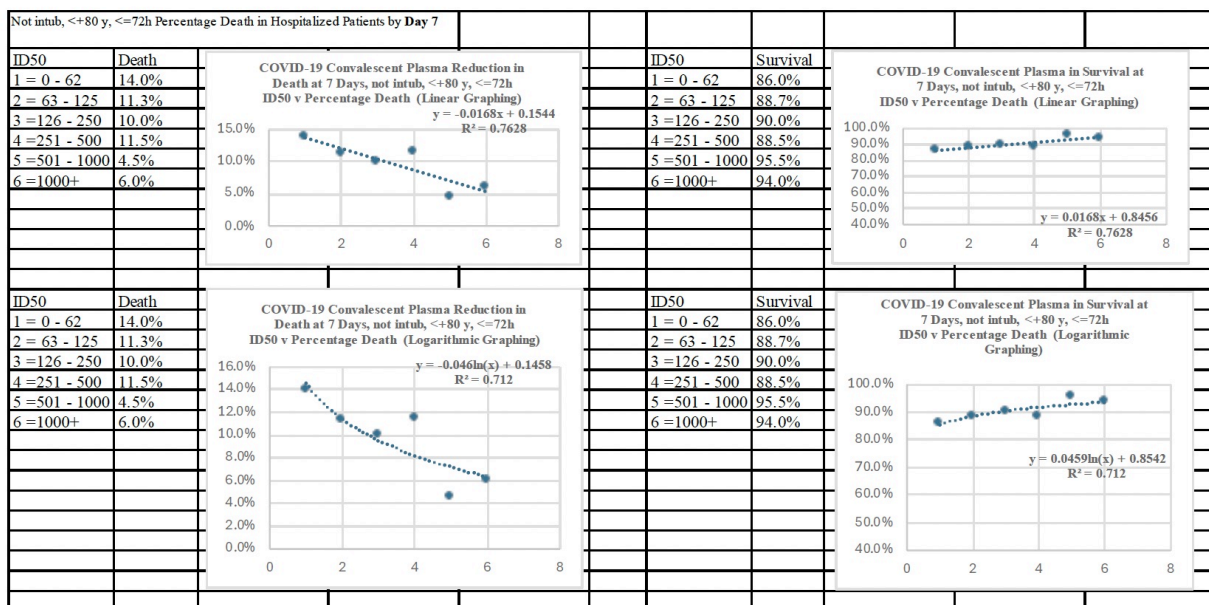
1. **Severity of Disease: Non-intubated:** means that on the average, these individuals were less severe in the viremic¹⁸⁶ (initial) phase of the disease (≤ 72 hours). Those undergoing treatment at >72 hours which is the phase of host response—the cytokine cascade and the bradykinin storm--the individual patient had progressed prior to administration of CCP to the full-blown COVID-19.¹⁸⁸⁻¹⁹⁶ The subsequent severe host response to COVID-19 of the initiation of the cytokine cascade and the bradykinin storm¹⁸⁸⁻¹⁹⁶ involves the interference of the renin-angiotensin system (RAS) as the coronavirus, SARS-CoV-2 entry into the pneumonocytes is associated with the ACE-2 receptor.
2. **Time: ≤ 72 hours:** means that on average each unique individual was in the viremic¹⁸⁶ (initial phase) of the COVID-19 infection with the coronavirus, SARS-CoV-2.
3. **Age:** was associated with death correlating with an increasing slope rate of $\sim 0.5\%$ mortality by increasing year after age 49 (Graphs IV).¹⁸⁷ **What is not reported in the FDA's cursory report is a segmental analysis (e.g., by decades) correlated with survival**— (Unfortunately, this is speculatively, because the FDA probably could not report these as there were probably too-few patients (underpowered) to distribute in 2x2 contingency tables of some of the age-decade-dependent subgroups.) The Michaelson-Menten graphs of survival developed from that which was reported by the FDA are, in actuality, summations of a series of aged-dependent (e.g.: by decade of age) of Michaelson-Menten-like graphs. To be pathophysiologically-consistent, though, with large enough subgroups numbers (n), these subgraphs should demonstrate a series of age/decade-associated parallel logarithmic survival curves for those non-intubated and having been given CCP within <72 hours of initial diagnosis dependent on the patient subgroup numbers that allow for an adequate power ($\text{Power} = 1 - \beta$) in the Chi-square analysis.

Graphs I: COVID-19 Convalescent Plasma (CCP) in Mortality (and Survival) at 7-days after treatment reported by the FDA on August 23, 2020, plotted against increasing titer concentrations.¹⁶⁶



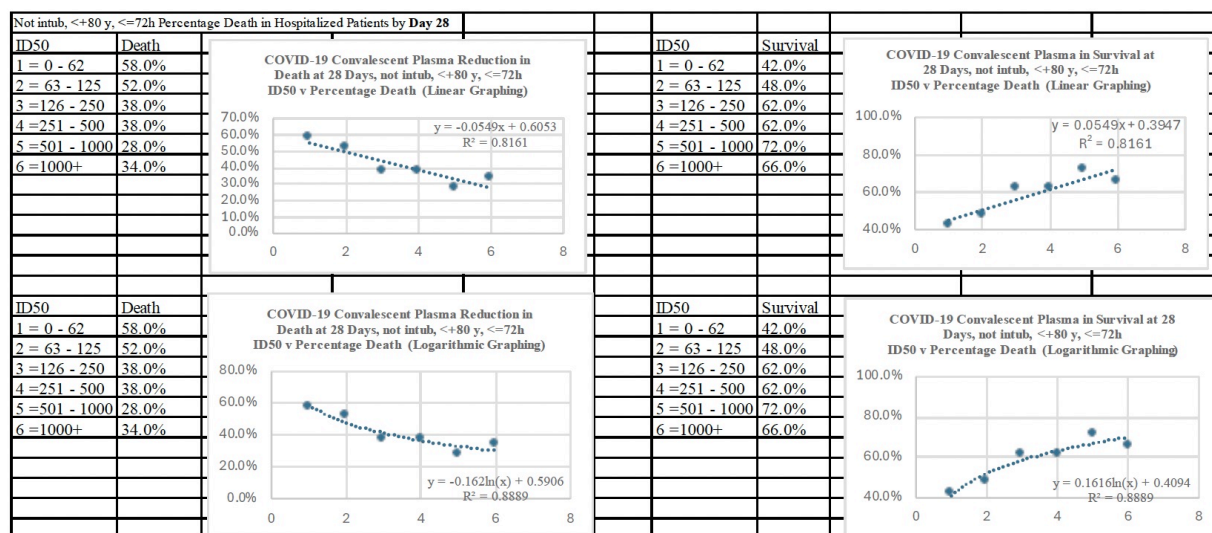
Graphs II: COVID-19 Convalescent Plasma (CCP) in Mortality (and Survival) at 7-days after treatment reported by the FDA in testimony before Congress on September 23, 2020, plotted against increasing ID50 of neutralizing antibody concentration ranges.¹⁶⁷

0.5 COVID-19 Convalescent Plasma Reduction in Death.xlsx



Graphs III: COVID-19 Convalescent Plasma (CCP) in Mortality (and Survival) at 28-days after treatment reported by the FDA in testimony before Congress on September 23, 2020, plotted against increasing ID50 of neutralizing antibody concentration ranges.¹⁶⁷

0.5 COVID-19 Convalescent Plasma Reduction in Death.xlsx



Graph IV, fig 1 and fig 2: Plots of Monthly Percentage Mortality from February 2020 to June 2021 reports of the CDC database of sex and mortality of COVID-19.¹⁸⁷

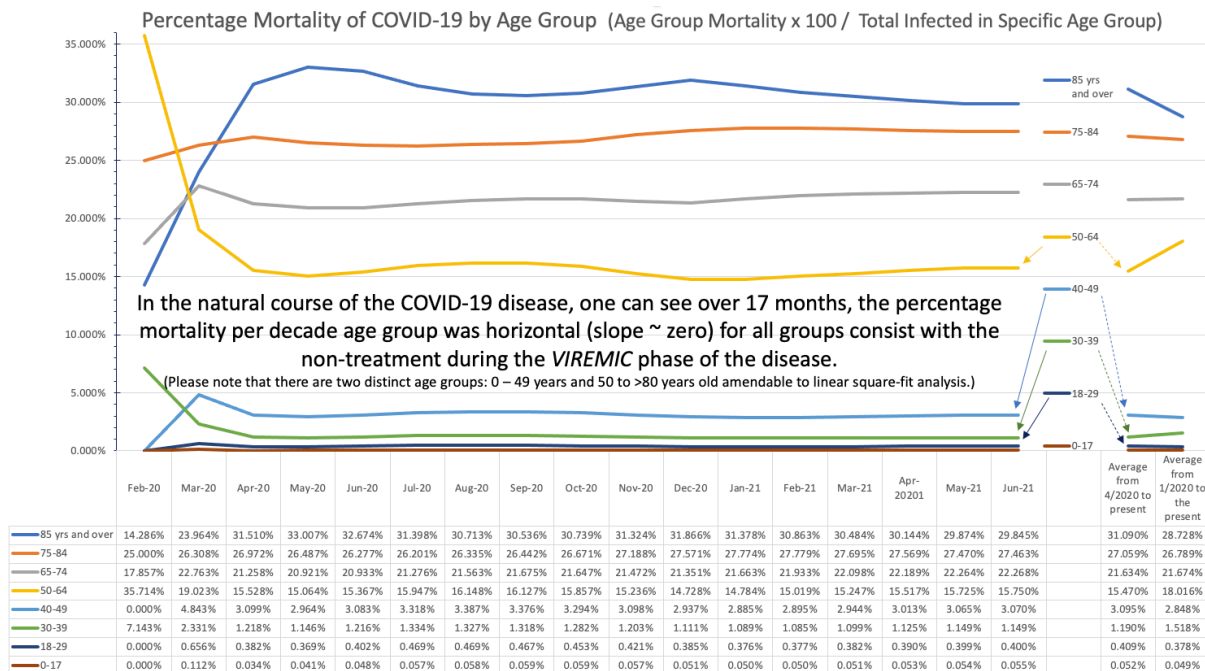
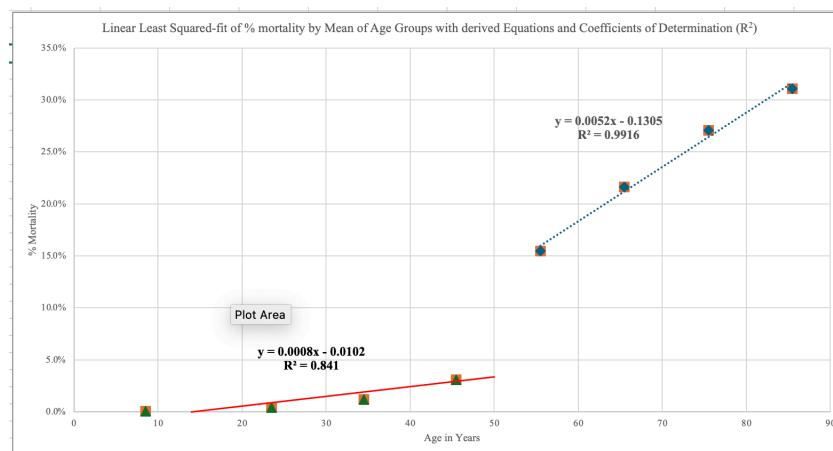


Fig 1: Y axis = monthly decade age group mortality due to COVID-19 total population of decade age group, Y axis = mortality rate in %. Data derived from the CDC database of sex and age mortality.

https://web.archive.org/web/20210217175653/https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAge ¹⁸⁷



0 – 49 years of age: Mortality rate (y) = $0.0008(x) - 0.0102$ $r^2 = 0.84$

50 – 90+ years of age: Mortality rate (y) = $0.0052(x) - 0.1305$ $r^2 = 0.99$

Fig 2 is derived from a calculated least-square fit of the data from Fig. 1. The slopes of the plots x 100 equals the fractional increase in mortality rate per year for the 0 – 49 age group of roughly 0.08% increase per age-year of the annual mortality and for the ≥ 50 age mortality of 0.52% increase per age-year of the annual mortality of ages are: 50 years of age, the calculated risk of mortality rate is: $[(0.0052 \times 50) - 0.1305] = 14\%$; 60 years of age, the calculated risk of mortality rate is: $[(0.0052 \times 60) - 0.1305] = 18.2\%$; and 70 years of age, the calculated risk of mortality rate is $[(0.0052 \times 70) - 0.1305] = 23.4\%$.

The cornerstone of U.S. Medicine’s denial of COVID-19 Treatment for all regardless of age or concomitant chronic illnesses (vs. Prophylaxis) in the addressing of COVID-19 was the need to discredit the usefulness of early (with 72-96 hour) administration of exogenous immunoglobulins (***Passive Immunization***) and antivirals during the viremic phase¹⁸⁶ to ALL who became infected with coronavirus, SARS-CoV-2. This is a foundational immunologic postulate regarding the effectiveness of **Passive Immunization** and antiviral therapies:

Table 4: Updated Evidence to Support the Emergency Use of COVID-19 Convalescent Plasma – as of 9/23/2020.¹⁶⁷

Updated Evidence to Support the Emergency Use of COVID-19 Convalescent Plasma – as of 9/23/2020										
BEST ITERATIONS										
	7-day						28-day			
	Lived		Death		p value		Lived		Death	p value
	7-day	Survival	7-day	Mortality			28-day	Survival	28-day	Mortality
Low titer Not Intubated	1002	86.08%	162	13.92%	1164		312	50.24%	309	49.76%
High titer Not Intubated	1178	88.97%	146	11.03%	1324		360	58.35%	257	41.65%
	2180		308		2488		672		566	1238
FDA reported					0.03					0.004
Iterated					0.0326					0.0044
	Lived		Death		p value		Lived		Death	p value
	7-day	Survival	7-day	Mortality			28-day	Survival	28-day	Mortality
Low titer Not Intubated, ≤80 y, ≤72 h	408	88.70%	52	11.30%	461		130	53.50%	113	46.50%
High titer Not Intubated, ≤80 y, ≤72 h	442	93.64%	30	6.36%	471		161	66.53%	81	33.47%
	850		82		932		291		194	485
FDA reported					0.008					0.004
Iterated					0.0079					0.004
https://www.fda.gov/media/142386/download										

Discussion:

U.S. Medicine's response in the treatment (not prophylaxis) in the United States epidemic of COVID-19 was disorganized, leaderless, downright sloppy, and highlighted our failure to remaining true to our Hippocratic Oath: *Primum non Nocere* – First, do no harm.¹⁹⁷ The NIH (especially the NIAID), the FDA, the CDC, the PHS, the VA, U.S. Academic Medicine, medical publications like JAMA and NEJM, etc. should be ashamed for not developing, appropriately publicizing, and universally implementing an organized approach to the early treatment (≤ 72 hours of diagnosis/symptomatology) by utilizing (1.) **Passive Immunization**^{16,22,33-38, 46,47,127, 190, 198-201} **synergistically**^{129,196,202-204} with (2.) **antivirals**^{16,37,128-130,145,148-157,186,196,202-211} in the drive to mollify the severity outcomes of coronavirus, SARS-CoV-2, COVID-19 infections in all newly-infected individuals. For all non-infected individuals, Active Immunization^{10-14,16,35,127} (vaccination) should be universally administered; and, if Passive Immunization was given previously to those acutely infected with COVID-19 or having sustained close-contact exposure, then subsequent *Active Immunization* (vaccination) should be administered ~8 weeks later.

While alluded to throughout the last five years, **no organized, statistically-significant protocol for the early treatment** (≤ 72 hours from diagnosis/symptomatology) was championed or implemented by U.S. Medicine. For over a century though, early treatment (within 72 hours of diagnosis) of the viral-naïve, acutely-infected individual with the use of exogenous immunoglobulins (**Passive Immunization**) and **antivirals** have been and should be the Standard of Care. Throughout the last century, the fundamentals of the acute Treatment (not Prophylaxis) of Infectious Diseases are based foundationally on three concepts:

1. Antibiotics and Antivirals administered with multiple doses over 5 to 10 days ASAP
2. Exogenous Immunoglobulins, e.g.: convalescent plasma and sera, gamma-globulin, IVIG, polyclonal antibodies, monoclonal antibodies, etc. [single dose (if adequate high-titer) – the *Magic Bullet* theory^{38,212} versus multiple doses of low-titer to summate to high-titer dosing ($C_1 \times V_1 = C_2 \times V_2$)].

The simple titration equation: $C_1 \times V_1 = C_2 \times V_2$ or, in terms of exogenous immunoglobulins:

$$\text{Antibody titer}_1 \times \text{Volume}_1 = \text{Antibody titer}_2 \times \text{Volume}_2,$$

can be used to calculate a cumulative total high-dose administration using multiple doses of low-titer CCP where C is the concentration of a solution (e.g.: moles of substance, titers of antibodies, etc.) and V is volume of the solution (e.g.: ml, L, oz, etc). The equation above is the mathematical construct for the basis of all titrations—including Clinical Immunology:

Conversion Low Dose COVID-19 Convalescent Plasma to High Dose COVID-19 Convalescent Plasma (CC-FFP) by increasing administration volume^{Ref 93, page 29:}

Titer of a Dose (200 ml) of CC-FFP	C1: Relative Polyclonal Antibody Units (RPAU)	V1: Std Volume of CC-FFP (200 ml = 1/2 unit of CC-FFP)	C1 x V1= RPAU x 200 ml STD RPAU in STD VOL	C1 x V2= RPAU x 400 ml	C1 x V2= RPAU x 800 ml	C1 x V2= RPAU x 1600 ml
		std dose vol	RPAU x 200 ml = 1/2 unit of CC-FFP	RPAU x 400 ml = 1 unit of CC-FFP	RPAU x 800 ml = 2 units of CC-FFP	RPAU x 1600 ml = 4 units of CC-FFP
Very low titer -- <1:80 dilution	<80					
Low titer -- 1:80 dilution	80	200	16,000	32,000	64,000	128,000
Low titer -- 1:160 dilution	160	200	32,000	64,000	128,000	256,000
Low titer - 1:320 dilution	320	200	64,000	128,000	256,000	512,000
High titer -- 1:640 dilution	640	200	128,000	256,000	512,000	1,024,000
High titer -- 1:1280 dilution	1280	200	256,000	512,000	1,024,000	2,048,000
High titer -- \geq 1:2560 dilution	2560	200	512,000	1,024,000	2,048,000	4,096,000

Based on the FDA presentations of August 23, 2020 and September 23, 2020.¹⁶⁶⁻¹⁶⁷

3. Optimization of Synergy of antibiotics or antivirals with exogenous immunoglobulins (versus the humanly-inherent naïve wish of *The Magic Bullet* of one agent and one time only.

- A. Active Immunization:** Administration of exogenous specific antigens (Ag) by vaccination to produce endogenous antibodies (Abs) in the non-infected individual against those specific antigens (Ag). Normally, what is thought of as a vaccination, is a stimulation within the individual of B-cell development to produce endogenous antibodies (e.g: IgM, IgG, IgA) to specific Ags presented to the individual being vaccinated. In the individual, development of IgG against some Ag of the COVID-19 requires roughly two weeks for full effective immunologic response. With the time delay of the development of adequate amounts of endogenous IgG in the COVID-19 individual over two weeks, vaccination (Active Immunization) is *prophylaxis* limited to non-infected individuals (not *treatment* of actively, acutely infected individuals). As the most effective time of IgG viral replication-suppression is during the viremic phase of COVID-19 (<72 - 96 hours from diagnosis) and not later during the time of cytokine cascade and bradykinin storm, there is limited efficiency of *Active Immunization* when administered to acutely, symptomatic, infected individuals. Active immunization of systemic vaccines long-term act through a complex cellular/humoral mechanism to address systemically the viremia early in the course of the disease (72-96 hours) with endogenous immunoglobulins in the vaccinated individual. In the case of respiratory viruses like COVID-19, nasal resistance to the SARS-CoV-2 virus is due to the development of mucosal IgA and not due to systemic immunoglobins, IgM and IgG, previously resultant from vaccination or previous systemic infection. While mucosal IgA, requires only ~5 days after COVID-19 nasal exposure to reach adequate levels, IgA protection is limited both due to the proximity to the nares mucosa initial exposure and has a short half-life long-term thus being ineffective for subsequent exposures without nasal reinoculation.
- B. Passive Immunization:** Administration of exogenous antibodies (not exogenous antigens) to provide immediate systemic immunologic response (IgG) from a donor (convalescent plasma or serum or polyclonal antibodies, or monoclonal antibodies). Application of *Passive*

Immunization is treatment not prophylaxis when administered (within 72-96 hours of diagnosis) to an newly infected individual. The *in vivo* persistence of *Passive Immunization* is dependent on the $\frac{1}{2}$ decay over ~21 days and, thus, utilization of *Passive Immunization* as a prophylactic agent is limited to the $\frac{1}{2}$ life decay of the exogenously administered antibodies. (See Attachment I regarding Respiratory Syncytial Virus (RSV) therapeutics) A naturally occurring form of *Passive Immunization* is the passage of maternal antibodies across the placenta to the fetus. Passive immunization when given early has been the mainstay for the treatment of infections for over a century especially when pharmacologic antibiotics or antivirals have not been available. When antiviral pharmacologic agents are available, passive immunization can also be used successfully synergistically in the viral-naïve infected individual. Convalescent plasma and sera, polyclonal antibodies, and monoclonal antibodies; γ -globulin, IVIG, etc.; and other specific plasmas and sera (Pasteur's rabies vaccine, hypertet, RhoGam, antivenoms, etc.) are all effective variations of *Passive Immunization*)

As has been extensively outlined in the **Results** section and confirmed by back-calculating iterations of the FDA's published results of August 23, 2020, and September 23, 2020, COVID-19 Convalescent Plasma when analyzed and reported by the FDA in the administrations of >94,000 units through the Mayo Clinic/FDA Protocol was statistically significant in decreasing mortality (thus increasing survival) when given in high titer administrations in less or equal to 72 hours from the time of diagnosis/symptomatology.¹⁶⁶⁻¹⁶⁷ There are at least thirteen articles (listed below in chronological order)¹⁶⁸⁻¹⁸⁰ that have been published from the Mayo Clinic / FDA Protocol of whom, the Principal Investigator (PI) was Michael Joyner, M.D., Ph.D. The Mayo Clinic / FDA Protocol was abruptly, inadvertently discontinued on August 23, 2020, due to the issuing of an EUA²¹³ regarding CCP that was headlined in *The White House* press conference directed by President Trump.²¹⁴ The universal general conclusion of reports resultant from the Mayo Clinic /FDA Protocol can be summarized in the following statement from the article¹⁷⁶: Klassen SA, Senefeld JW, Johnson PW, Carter RE, Wiggins CC, Shoham S, Grossman BJ, Henderson JP, Musser J, Salazar E, Hartman WR, Bouvier NM, Liu STH, Pirofski LA, Baker SE, van Helmond N, Wright TS, Fairweather D, Bruno KA, Wang Z, Paneth NS, Casadevall A, Joyner M: The effect of convalescent plasma therapy on COVID-19 patient mortality: Systematic review and meta-analysis. Mayo Clin Proc, 2021 May; 96 (5): 1262-1275. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7888247/pdf/main.pdf> :

CONCLUSION This real-time systematic review and metaanalysis of contemporaneous studies highlights that the mortality rate of transfused patients with COVID-19 was lower than that of nontransfused patients with COVID-19 and suggests that **early transfusion of high-titer plasma represents the optimal use scenario to reduce the risk of mortality among patients with COVID-19.** These results favor the efficacy of convalescent plasma as a COVID-19 therapeutic agent.

In the heat of the moment, though, during the terminal controversy in early 2021 over the effectiveness of early-administered COVID-19 Convalescent Plasma, Carlos H. Villa, M.D., PhD, Medical Officer, OBRR/DBCD/CRS wrote¹⁸¹ to Nicole Verdun MD, Director, OBRR of the U.S. Food & Drug Administration (FDA) [the OBRR is the Office of Blood Research and Review, which is part of the Center for Biologics Evaluation and Research (CBER) within the Food and Drug Administration] acknowledging both the positives and negatives of CCP administration but **concluded that it is all about three independent variables:**

- (1) the concentration of exogenous CCP
- (2) the timing of administration of exogenous CCP during the viremic phase of COVID-19, and
- (3) the individual human's endogenous immunological response to the infection (Table 3)

This present **undated** FDA memorandum¹⁸¹ that can be found on the Internet is: <https://www.fda.gov/media/141480/download> was **an overwriting of the original document of August 2020**¹⁸², which had been instrumental in the change of the published FDA Guidance on COVID-19 Convalescent Plasma of September 2, 2020.²¹⁵ This overwriting of the document issued in August 2020²¹⁶ which was the basis for *The White House* press conference on August 23, 2020, directed by President Trump¹⁶⁴, is confirmed as the quoted which anachronistically uses as documentation an article in the 2021 future: Lister et al²¹⁷ which ironically was published by the *New England Journal of Medicine* on the date of the June 6th, 2021 Insurrection²¹⁸:

Libster R, Pérez Marc, Wappner D, Coviello S, Bianchi A, Braem V, Esteban I, Caballero MT, Wood C, Berrueta M, Rondan A, Lescano G, Cruz P, Ritou Y, Fernández Viña V, Alvarez Paggi D, Esperante S, Ferreti A, Ofman G, Ciganda A, Rodriguez R, Lantos J, Valentini R, Itcovici N, Hintze A, Oyarvide ML, Etcegarary C, Neira A, Name I, Alfonso J, López Castelo R, Caruso G, Rapelius S, Alvez F, Etchenique F, Dimase F, Alvarez D, Aranda SS, Sánchez Yanotti C, De Luca S, Baglivo J, Laudanno S, Nowogrodzki F, Larrea R, Silveyra M, Leberzstein G, Debonis A, Molinos J, González M, Perez E, Kreplak N, Pastor Argüello S, Gibbons L, Althabe F, Bergel E, Polack FP, for the Fundación INFANT-COVID-19 Group*: Early high-titer plasma therapy to prevent severe Covid-19 in older adults, ClinicalTrials.gov, NCT04479163. New Engl J Med, NEJM.org, DOI: 10.1056/NEJMoA2033700, January 6, 2021, 1-9. <https://www.nejm.org/doi/pdf/10.1056/NEJMoA2033700?listPDF=true> Republished N Engl J Med, February 18, 2021; 384(7): 610 – 618.

This *ex post facto* reference of Villa¹⁸² with the overwriting of the original August 2020¹⁸¹ document is allegedly an illegal OVERWRITING of a Federal Policy lost to history by its inherent undated anonymity. This anachronistic OVERWRITING is a violation of the Sarbanes-Oxley Act of 2002, PL 107-204, 18 U.S.C. §1512(c)(1)¹⁰³ -- that may have innocently and publicly mollified the FDA's original position at the time in February 2021 but has covered-up for all of history and misdirected all future teachings and applications by U.S. Medicine of the clinical science of *Passive Immunization* by its undated *de facto* anonymity. The opening sentence in the June 28, 2024 opinion of the Supreme Court of the United States in *Fischer v. United States*¹⁰⁴ reiterates that it is illegal to alter, destroy, mutilate, or conceal a Federal record, document, or other object:

The Sarbanes-Oxley Act of 2002 imposes criminal liability on anyone who corruptly “alters, destroys, mutilates, or conceals a record, document, or other object, or attempts to do so, with the intent to impair the object’s integrity or availability for use in an official proceeding.” 18 U.S.C. §1512(c)(1)

As was successfully promoted by the WHO in the 1970s for the complete eradication of smallpox in the 1970s, **an epidemiology of synergy** of a combination of (1) coordinated treatment of **ALL** acutely infected individuals with exogenous immunoglobins (*Passive Immunization*) and antivirals and (2) prophylaxis with vaccines (*Active Immunization*) of all non-infected individuals immediately or after a period of time (~8 weeks) if they received exogenous

immunoglobulins due to their high-risk of exposure should have been implemented in our addressing of COVID-19.²¹⁹⁻²³⁵ Such an epidemiology of synergistic treatment and prophylaxis should today be emulated in the now ongoing threat of M-pox (monkey pox)²³⁶⁻²³⁹, in our addressing of respiratory syncytial virus (RSV) (**Attachment I**), and in treating all future viral threats. In varying degrees, the antithesis to **synergy**^{129,196,202-204} in the treatment of infectious diseases is our century-old, naïve belief in the “*Magic Bullet*”^{38,212} only: i.e., our expectations in the treatment of diseases are that we will find one agent that will eradicate the disease 100% of the time in the infected individual. A century ago, the Noble Prize in Medicine or Physiology was awarded to Paul Erlich in 1908 for his concept of chemotherapy (i.e.: specific chemical/drug therapy in the treatment of disease).²¹² The most outstanding, successful example of the *Magic Bullet* was Sir Alexander Fleming’s discovery of penicillin for which he was awarded the Noble Prize in Medicine or Physiology in 1945.²⁷ Our quest for magic bullets has truly advanced medicine over the last 100+ years but that very mindset of discovering the next magic bullet has also delayed the utilization of the synergistic treatment of diseases with combinations of somewhat-less-than-effective single magic bullets at the same time—even, though, such synergy may be much more clinically successful than any single magic bullet.²⁴⁰⁻²⁴² Some examples of synergistic treatment of infectious diseases in the present day include, e.g.: the treatment of gram negative organisms, tuberculosis, drug resistant microbes, HIV, hepatitis C, etc. The synergistic use of antivirals, immunotherapy, and immunomodulation has been suggested to be most successful in COVID-19 especially when given during the viremic phase of the disease (roughly less than 72 hours from diagnosis/symptomatology).

There is a trail of clinical-treatment-policy missteps which would be sadly comical if there was not cumulative layers of disregard and blatant contradiction to medical fundamentals, chronic denial (Attachment V), political self-centeredness, narcissism, ignorance bordering on stupidity, and just-plan meanness that were put-in-play in March/April 2020, that has continued over the last five years, and are still perpetuated into the future. A summary of COVID-19 pathophysiology and an abbreviated timeline of immunoglobulin and antiviral therapy can be found in:

Andrus CH: Book 4: President Biden’s July 7, 2023 Response Letter to Dr. Andrus’ submission of 2023-04-27 update 11-7-13.pdf. 0.2 2022-09-11 Dear Mr President Case Report and COVID-19 pathophysiology. 1 – 74 pages. <https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attempt-2024-03-05>, e56 – e130.⁹³

On July 7, 2023, President Joseph Biden replied to the included summary submission of Book 1: Dear Mr. President: COVID-19 and Where We Went Wrong. <https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02/>⁸⁵

Book 1 is 1266 pages documenting correspondence with the NIAID, the FDA, the VA, and The White House over 3 years concerning the clinical care of patients newly infected with COVID-19. All the documentation that has been submitted to the NIH NIAID Case #12276 (Book 1 is an abridged documentation) is available through the Freedom of Information Act Officer of the NIAID. The submissions to the NIAID and FDA in detail outlined the pathophysiology of coronavirus SARS-CoV-2; the difference between Active Immunization (vaccination for PROPHYLAXIS to stimulate endogenous immunoglobulins) vs Passive Immunization in the TREATMENT of acute COVID-19 within 72 - 120 hours of diagnosis] through the administration of exogenous immunoglobulins, e.g.: Convalescent Plasma, Monoclonal Antibodies, and Monoclonal Antibody cocktails, etc.); describe extreme misinformation and obfuscation by the NIH, NIAID, FDA, etc.; describe in-depth the inappropriate late timing of administration of immunoglobulins and antivirals (>120 hours from diagnosis of acute infection); and the cover-up by governmental, academic, etc. entities by electronic overwriting, URL site relabeling/renaming, and website removal; officials, medical researchers, academics, and clinicians, and agencies advancing incorrect or misleading medical statistics and theories that were associated with and were possibly contributory to >1,000,000 reported deaths from COVID-19 in the U.S.A. from March 2020 to the present. -- Charles H. Andrus, M.D., F.A.C.S.

Throughout March 2020, six misadventures in the (1) treatment implementation, (2) subliminal withholding or rationing of treatment implementation, (3) an establishment of general therapeutic abandonment policy and treatment, and (4) unintentional denial of patient rights set the stage for all that would follow:

1. **March 2, 2020, The Outline of Addressing the U.S. response to the COVID-19 Pandemic:** At the meeting in *The White House* between the President and Vice-President of the United States and Federal Physicians who would become members of *The White House* Commission on the COVID-19 and representatives of Pharmaceutical / Biologics Corporations (Table I), the concept of early treatment (<72 hours) with *Passive Immunization* and *Antivirals* was minimized in favor of primarily rapid vaccine (*Active Immunization*) development and deployment throughout the nation. With the absence of representation of the American Red Cross and the American blood banks, and the following euphemistic misstatement regarding *Passive Immunization*,

2020-03-02 The White House: Remarks by President Trump and members of the coronavirus task force in meeting with pharmaceutical companies.

- 1.) Transcript: <https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-members-coronavirus-task-force-meeting-pharmaceutical-companies/>
- 2.) Entire meeting video: <https://www.c-span.org/video/?469926-1/president-trump-meeting-pharmaceutical-executives-coronavirus>
- 3.) Video of Dr. Schleifer's euphemistic explanation of *Passive Immunization*: https://www.youtube.com/watch?v=3li6p_stzW8:

DR. SCHLEIFER: Thanks, Mr. President, for having us. I'm Lenny Schleifer, the founder and CEO of Regeneron, a company that I built with George Yancopoulos over the last 30 years. And we are a monoclonal antibody primarily centered company. We are no strangers to collaborating with the administration. We work with Secretary Azar's group, BARDA. And we came up with a cure for Ebola, and we're very proud of that. Dr. Fauci's group was really instrumental in testing that under unbelievable conditions in the Congo. And it didn't create quite as much excitement, because, thank goodness, it didn't hit our shores.

But we can use the exact same technology, and we already have. We have 1,000 antibodies that are already sitting in dishes. We're screening them. We're selecting them. We anticipate, if all goes well, 200,000 doses per month can come out of our factory in New York, starting in August.

The unique thing about our technology —

THE PRESIDENT: That means you'd be able to use the vaccine that early?

DR. SCHLEIFER: It depends on what we see; how we work closely with the FDA, which we will do. The FDA already reached out to us, but we've got to work closely.

THE PRESIDENT: So that process would be faster than John's?

DR. SCHLEIFER: It would be. The —

SECRETARY AZAR: Can you explain why that would be?

DR. SCHLEIFER: Well, so, we make **passive vac- — vaccine** and therapeutic — therapeutic. Our drug will be able to protect you. Whether or not you're infected, it'll protect you from getting infected. Or if you are infected, it would treat you. And the — we have just taken processes that normally take years — literally, years — and we put them end-to-end and now do them in weeks to months, which nobody else in the industry can do.

So we're very excited to collaborate once again.

THE PRESIDENT: So this would be a combination of a vaccine and also it will — to put it in a different way — make you better, quicker.

DR. SCHLEIFER: Yeah. Well, think of it this way: If you — if you get immunized with one of these vaccines, you're going to make some antibodies to protect you. We're going to already make those antibodies and give them to you so you don't have to go through that whole process. So it'll protect you.

And, as we showed with Ebola, if you give enough of them — we — it was lifesaving, life- — truly lifesaving.

THE PRESIDENT: That's true.

DR. SCHLEIFER: And it beat out the antivirals. It really — it was the way to go. It's very predictable.

I just want to say, I hope everybody succeeds here. I mean, this is — bringing everybody together here is really critical and there's going to be success. This industry is really talented, as an industry. Sometimes we run astray, but we're going to get this done.

THE PRESIDENT: Thank you very much. Thanks, Len. Appreciate it. Please.

the future American public and medical mindset became tainted with the minimization of the ethical importance of early-in-the-course-of-the-disease treatment (<72 hours from diagnosis) **SYNERGITICALLY** with immunoglobulins (*Passive Immunization*) and antivirals for **ALL** acutely infected with coronavirus, SARS-CoV-2, versus therapeutic abandonment favoring instead prophylaxis of the “herd” with anticipated vaccines (*Active Immunization*) and mass inoculations in the future.

2. **March 13, 2020: Proclamation of the Public Health Emergency (PHE):** xxx
3. March 17, 2020: Suspension of parts of EMTALA
4. March 18, 2020: Surgeon General advocates staying away from hospitals
5. March 24, 2020: EUA regarding Convalescent Plasma with rationing criteria is announced by the FDA
6. March 26, 2020: The British Medical Journal (BMJ) documents rationing criteria. Due to the removal/overwriting of the URLs, all three references point to *ex post facto* sources
7. April 4, 2020: Michael Joyner, M.D., PhD, becomes the Principal Investigator of the Mayo Clinic /FDA COVID-19 Convalescent Plasma program
8. May 1, 2020: EUA for Remdesivir

7.0 2021-09-19 Timeline of U.S. Government Regarding Passive Immunization and the Discrediting of COVID-19 Convalescent Plasma is a more complete outline sent to President Biden in September 2021.³⁷ pages 290-292.

Dear Mr. President:

Please excuse my forwardness in submitting this cover letter to you but it is of major importance and my duty as a federal physician to appraise you of this. As Dr. Birx said in her interview with Margaret Brennan on face the nation on January 24, 2021, this may never come out in her lifetime. The bottom line is that US medicine and the executive branch of the federal government in March 2020, abandoned the America people by NOT offering **Passive Immunization** as the immediately available treatment of COVID-19, future synergistic treatment with **Active Immunization** in all that contract COVID-19 after vaccination, and a prophylaxis for high-exposure individuals like healthcare workers, first responders, grocery clerks, immune suppressed individuals and everyone else. The timeline of the failure of U.S. Medicine, U.S. Research, and the U.S. Government regarding **Passive Immunization** is as follows:

1. On March 3/2/2020, leaders of Pharma, the FDA, the NIH, etc. met with President Trump and failed to make the distinction of **Active Immunization versus Passive Immunization**. https://www.youtube.com/watch?v=31i6p_stzW8

2. President Trump declared an emergency on March 13, 2020.
<https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>
3. Secretary Azar on March 13, 2020 suspended parts of EMTALA retroactive to March 1, 2020. <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>
4. China sends medical team to Italy to set up 50 blood collection centers to help in treatment of COVID-19.
<https://www.chinadaily.com.cn/a/202003/14/WS5e6bd352a31012821727f096.html>
5. On March 19, 2020, Johns Hopkins Bloomberg School of Public Health carries story of China offering to Italy 90 tons of COVID-19 Convalescent Plasma (~500,000 doses).
<https://www.globalhealthnow.org/2020-03/covid-19s-stop-gap-solution-until-vaccines-and-antivirals-are-ready>
6. On March 24, 2020, **FDA Failure because** instead of the FDA declaring **Passive Immunization** synergistic with future vaccination (active immunization--vaccination) and declaring convalescent plasma (a Nobel Prizing winning passive immunization, 1901) a biosimilar biologic to e.g.: rabies vaccine, RhoGAM gamma globulin, IVIG, tetanus hyper immune globulin, etc., the FDA declared **COVID-19 convalescent plasma investigational**. (i.e.: **EXPERIMENTAL**)
https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf
7. In order to make convalescent plasma immediately available the FDA authorized **expanded access (COMPASSIONATE USE)** through six programs in the United States WITH most visible that through the Mayo Clinic in which over >2700 hospitals would participate.
<https://web.archive.org/web/20200404010134/https://www.uscovidplasma.org/> By the definitions of the NIH and FDA “Expanded Access” is “Compassion Use” (**DATA NOT AVAILABLE TO BE USED FOR CLINICAL TRIALS**) which means that any data from the administration of over 94,000 doses by the Mayo Clinic from March 24, 2020 to EUA of August 23, 2020 should not have been used as data for research studies. (The vast majority of **CCP administrations were given late in the disease at the WRONG TIME.**)
8. On March 24, 2020 the FDA announced inclusion criteria for administration of COVID-19 convalescent plasma which was wrong giving it only when the patients were on death’s door with the FDA referencing their misinterpretation of an Chinese epidemiology paper published in February 2020. (**The FDA removed the reference in all subsequent documentations and failed to tell the American public they were administering CCP at the WRONG time.** The FDA quietly removed the WRONG inclusive criteria from all subsequent documentation on September 2, 2020.) Passive immunization has only been shown to be most successful in previous epidemics when given within the first 72 hours of diagnosis—NOT at death’s door!
https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf
9. **For the last 18 months the FDA has made all the agents of passive Immunization experimental (Investigational) by issuing EUAs.** In so doing they violated the intent (and really the letter of the law) of PL-115-176, the Right to Try Law

<https://www.govinfo.gov/content/pkg/PLAW-115publ176/pdf/PLAW-115publ176.pdf> in limiting the ability of patients to request **Passive Immunization** agents –thus, abandoning / withholding treatment of the American people within 72 hours of contracting COVID-19.

10. CCP was issued its first EUA on August 23, 2020 while still under the restrictive late-in-the-disease inclusion criteria of March 24, 2020. The FDA quietly rescinded this wrong inclusion criteria on September 2, 2020 and then did not notify the American public. (The FDA also quietly rescinded the same inappropriate inclusion criteria regarding Remdesivir on August 28, 2020.). President Trump in the first 2 minutes of the White House Press Conference insulted China by referring to the coronavirus SARS-CoV-2 virus as the **CHINA virus**. (China stopped their epidemic by quarantine and liberal use of CCP. How does one know this?--In March 2020, China sent 15 medical personnel to Italy to assist in the development of CCP infusion centers and **China offered 90 tons of surplus CCP to the Italians**.)
11. October 2, 2020 President Trump was diagnosed with COVID-19, and within four hours President Trump was given Regeneron monoclonal antibody cocktail and within 18 hours began Remdesivir infusions. Subsequently, it is documented that former Governor Christie, former Mayor Giuliani, and former HUD Secretary Dr. Ben Carson received at least monoclonal antibodies. **While every person in the United States who turned positive for COVID-19 should have been eligible for early administration of this combination of monoclonal antibodies and Remdesivir, it was concealed in plain sight** from the American people by agencies of the Executive Branch of the Federal Government by not announcing its significance formally to the American people.
12. In November 2020 the VA issued the incorrect timely--administration inclusion criteria for Remdesivir (Velkury), which had been approved as a prescription drug on October 22, 2020 by the FDA. The VHA still lists this incorrect administration criteria continuing to this day on the Internet to this day. At the time, I was in e-mail communications with VHA Chief Medical Executive, Richard Stone, M.D., (really VHA Under Secretary of Health although I am not sure he was approved by Congress) and *The New England Journal of Medicine*.
13. On January 6, 2021, *The New England Journal of Medicine* published the **only prospective, randomized, placebo-controlled, appropriately timed (<72 hours from diagnosis administration), age-stratified CCP administrated article** for the last 18 months. This “landmark” article definitively demonstrated that when CCP was administered early (<72 hours from time of diagnosis) and compared with placebo in 70 year old patients, the decrease in hospitalization was significant ($p < 0.03$) and the morality was halved (CCP=2 vs. placebo=4) but did not reach significance as the study was too small.
14. On January 24, 2021, Dr. Birk’s was interviewed by Margaret Brennan on *Face the Nation*. <https://www.youtube.com/watch?v=odklJGnhvhU>
15. On February 1, 2021, I e-mailed the FDA, NIH, *The New England Journal of Medicine*, and many pertinent persons (*reducio-ad-absurdum*) pointing out Dr. Birk’s plea.
16. On February 4, 2021, the chief scientist of the FDA, RADM Denise Hinton issued a new EUA for Convalescent Plasma (*vis-a-vis* coinciding within 48 hours of my letter to Dr. Birx).

17. Within 24 hours, Peter Marks, M.D., Chief of the Biologic Division of the FDA is quoted in the WSJ with conflicting remarks about convalescent plasma. He then issues an official statement from the FDA and in an interview three weeks later praising CCP.
18. In the NEJM on February 18, 2021, Dr. Katz Acting Director of the Mississippi Valley Blood Authority (now renamed ImpactLife) prints a three page light-hearted, obfuscating editorial entitled: (A Little) clarity on convalescent plasma for COVID-19.
19. In February 2021, BARDA announces it will defund CCP throughout the nation.
20. March 8, 2021, ImpactLife to phase out CCP donations (~120 hospitals in the Midwest)⁴⁸⁴
21. The NIH quotes an underpowered study (results not published) regarding a non-age-stratified placebo-controlled ER study on CCP administration that was closed early because they could not recruit even patient's for the placebo study.
22. March 10, 2021: Convalescent Plasma Strikes Out as COVID-19 Treatment.
<https://www.npr.org/sections/health-shots/2021/03/10/975365309/convalescent-plasma-strikes-out-as-covid-19-treatment>
23. April 21, 2021: NIH COVID-19 Treatment Guidelines panel recommends against COVID-19 Convalescent Plasma.
<https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/convalescent-plasma/>
24. Regeneron teams up with ROCHE International to market REG-CoV-2 (monoclonal cocktail to the world). (ROCHE is selling REG-CoV-2 to Indian hospitals for 50,000 Repees (~\$800) for those that can afford it to be given early in the course of the disease. On-the-street it is referred to as the "Trump cocktail")

---this outline is incomplete but is included as it is an extensive timeline on how COVID-19 Convalescent Plasma was discredited from March 2, 2020 to April 2021.

The timeline of the failure of U.S. Medicine, U.S. Research, and the U.S. Government regarding **Passive Immunization** can be found in Table 1 regarding CCP and that for the antiviral Remdesivir: Andrus CH: *Dear Mr. President: COVID-19 and Where We Went Wrong*. Internet Archive, publication date 2023-09-12, pages e9 – e14. <https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02> ³⁷

There are already several books by individuals and groups rendering their versions of what transpired over the course of the American COVID-19 epidemic, where we went wrong, and how we should fix our failures in the future, e.g.:

1. Gottlieb S, Former FDA Commissioner: *Uncontrolled Spread—Why COVID-19 Crushed Us and How We Can Defeat the Next Pandemic*. New York: HarperCollins Publishers, 2021. <https://www.harpercollins.com/products/uncontrolled-spread-scott-gottlieb?variant=41042025545762> ²⁴³
2. Nash DB, Wohlforth C: *How COVID Crashed the System—A guide to fixing American Health Care*. Lanham, Maryland: Rowman & Littlefield, 2022.

<https://rowman.com/ISBN/9781538164259/How-Covid-Crashed-the-System-A-Guide-to-Fixing-American-Health-Care> ²⁴⁴

3. The COVID Crisis Group: *Lessons from the COVID WAR—An investigative report*. New York: PublicAffairs, 2023 April 25.
<https://www.hachettebookgroup.com/titles/covid-crisis-group/lessons-from-the-covid-war/9781541703803/?lens=publicaffairs> ²⁴⁵

The real tragedy in the American fight throughout the COVID-19 epidemic was that it was: (1) permeated with panic; (2) riddled with misinformation; (3) inappropriately politicalized with the notion that money can buy a cure, e.g.: Operation Warp Speed; (4) generalized inappropriate rationing based on age, concomitant diseases, etc.; and (5) lacked any organizational leadership and direction. Medically addressing a novel viral disease (i.e.: COVID-19) in the treatment of **EVERY** infected individual should be the highest priority for developing and implementing the science into foundationally anchored clinical methodologies. In short, the clinical response that should be afforded every potential and every infected patient should not be clouded in the intricacies of the molecular virology, overwhelmed by epidemiological theories, distracted by political or capitalistic philosophies, or consumed in frivolous rhetoric and *ad hominum* blame:

1. **Identify the agent** (i.e.: coronavirus, SARS-CoV-2, COVID-12) and elucidate the **pathophysiology of the disease** [e.g.: passage through the nares; entry into the pneumonocytes via the ACE-2 receptor; early development of the bilateral pneumonia symptomatology; the finite delay--which is a host rate-limiting-step--of developing adequate therapeutic serum titers of endogenous IgG (~2 weeks after contraction of the virus); the later-in-the-disease intrinsic activation of the cytokine cascade; the bradykinin storm in COVID-19 due to the affected renin-angiotensin system (RAS), etc.] **as it is related to the clinical disease**, etc. Within this initial first step, there is a constellation of processes and methodologies required:
 - a. Identify the mode of transmission(s) and establish practices of epidemiological protection: quarantine, isolation, PPE, masks based on the size of the virus, method of entry into the host, etc.—e.g.: (N95 masks mean that 95% of particles under 300 nm in size will be stopped; but COVID-19 is measured to be 80 – 120 nm in size.)
 - b. Develop testing methodologies that are reliable, easily deployed, and ideally meet a 0.95 confidence-level for sensitivity criteria of such “screening” tests for the populous. Using the AI program Perplexity, a summary of published sensitivities of the COVID-19 screening tests are outlined regarding RT-PCR, rapid antigen tests, and viral cultures. (**Attachment Q**)
2. Initiate Treatment:
 - a. Immunotherapy
 - i. Exogenous immunoglobulins as Passive Immunizations in both frontline treatment (within 72 hours of diagnosis/symptomatology) in infected patients (including previously vaccinated patients with symptomatology)

and in the treatment and prophylaxis of immunosuppressed patients, asymptomatic but infected patients, e.g.:

1. COVID-19 Convalescent Plasma and Sera
2. Monoclonal Antibodies and Monoclonal Antibody combinations
- ii. Exogenous antigens as Active Immunizations (vaccinations) in the prophylaxis for all immunological-naïve, non-infected individuals by stimulating the endogenous immune system of the patient
- b. Antiviral therapy in ALL infected patients regardless of their previous vaccination status, e.g.:
 - i. Veklury (Remdesivir)
 - ii. Paxlovid
 - iii. Etc.
- c. Supportive therapy: ventilators, ECMO, resuscitations, all ongoing care, etc., etc., etc.
- d. Chronic care.
3. Prophylaxis (Active Immunization/vaccination) for treatment of the “herd” of the American population which will prophylactically diminish future severity of illness, decrease the overall individual vector prevalence

In the end, U.S. Medicine in the treatment of those infected with COVID-19 was defeated by a non-sentient, non-living, complex chemical pathogen called coronavirus, SARS-CoV-2, COVID-19. We, as members of U.S. Medicine, failed at seemingly every turn:

We failed to bridge the gap between basic science and clinical medicine.²⁴⁶

We failed to base treatment on the pathophysiology of the disease.²⁴⁷

We failed to set our promise of *Primum non Nocere* for each and every infected patient in not promoting an appropriate treatment plan in ≤ 72 hours from diagnosis with exogenous immunoglobulins and antivirals for ALL (regardless of concomitant risk-factors or age) infected with SARS-CoV-2, COVID-19.¹⁹⁷

We lied to ourselves when it was self-beneficial--reflective of our self-centeredness—we repeatedly committed the seven deadly sins of medicine.²⁴⁸⁻²⁴⁹

We were not true to ourselves and we covered it up with *Chronic Denial*. Attachment V,122-124

All of you, as physicians, should have had the fundamental knowledge regarding early treatment (≤ 72 hours from diagnosis) of a novel virus with antivirals and synergistically with exogenous immunoglobulins.

Throughout this analysis, I have tried to emphasize that's the treatment of any novel virus of which we have no vaccine is still accomplishable if done within 72-96 hours of diagnosis with some form of exogenous immunoglobulins and synergistically with antivirals. Literally, after writing the FDA, the NIAID, the CDC, *The New England Journal of Medicine*, The VA, the

White House, etc. since April 5, 2020, it should be personally comforting to know that all final official admonitions are consistent with what I have written.--Well, it is not. It is truly sad that in the education of future generations of physicians and surgeons throughout the world, but especially in the United States of America, we have failed in organized instruction to teach and integrate basic science tenets in clinical practice that have their origins in the late nineteenth century. The teaching of fundamentals are seemingly separated from clinical practice by distances and depths akin to that seen between the South and North Rims of Grand Canyon National Park. The major Internal Medicine textbook, *Harrison's Principles of Internal Medicine*²⁵⁰, is probably not purchased by the vast majority of medical students today because they just don't purchase nor read hardcopy medical books anymore:

As one student said to me during a junior surgery class lecture on fluid and electrolytes several years ago—I don't need to pay attention because I can find it on my iPhones.

Today, our Medical Students aren't tested on their individual fund of knowledge developed from reading a textbook but rather on the abbreviated individual course syllabus or outlines, etc. In fact, at best, the present two volume *Harrison's Principles of Internal Medicine*²⁵⁰ is outstanding for pressing flowers! The medical student in many cases is never taught to analytically integrate fundamental knowledge into clinical practice because the fundamental knowledge provided is in a confused, disorganized, piece-meal manner.—Teaching at the Bedside has become haphazard at best, if not, completely passé.²⁵¹

With regards to immunotherapies in the treatment of novel viral diseases, medical students to practicing clinicians and the American public in general today are receiving their disjointed pharmacology training and integration with clinical medicine by being inundated with disjointed, paltering advertisements on television. What is needed is a new Flexner Report²⁵²—for Medical Schools, Residencies, and Academic, Research, and Clinical Practice. No one need worry, though, such a revolution in American Medicine will probably never occur--for few medical students, residents, and practicing clinicians today even know the history of the scientific development of American Medical Schools and Residencies beginning in the 1880's and its integration with clinical practice dating back to Johns Hopkins University and Sir William Osler, M.D. and William Stewart Halsted, M.D., F.A.C.S.²⁵¹

We live in the time of Machiavellianism: *The end justifies the means*.²⁵³ If we do not have fundamental guidelines that can be implemented in daily practice that are taught to neophytic physicians and surgeons of medicine based on foundational guidelines, analytical integration, and focusing on the individual care of every patient that presents, we, as clinicians of the humanity's most noble practice for eternity, have failed our trainees.

The *New England Journal of Medicine* (NEJM) speaks of the need for integrity in publishing medical articles.⁸⁰ It is my worry that NEJM will not publish this present article because it addresses the gaping holes in our medical training, the deep-divide between research and clinical Medicine today, and the disinformation of lies of commission, omission, and paltering that are pervasive throughout our society. Throughout our society especially in the Medical Science, fact and fiction have become blurred and fiction is entertained as a reasonable alternative. In my opinion, the previous Trump Administration and its COVID-19 White House Task Force²⁵⁴ in the index month of March of 2020 did a tremendous disservice to humanity as outlined above. The

concept of the single “Magic Bullet” in Medicine should go the way of the Dodo bird replaced by synergistic treatments.

In a collective subliminal validation of the application in clinical medicine of scientific foundational principles, the Mayo Clinic, the FDA, the NIH, and individuals like Dr. Birx, Dr. Fauci, Dr. Joyner, Dr. Casadevall, etc. all professed the answer in improved, consistent survivability in **the treatment** of COVID-19 (and, against all present and future viruses in which the individual is immunologically naive):

1. The initial treatment with exogenous immunoglobulins (***Passive Immunization:*** Convalescent Plasma / Polyclonal Antibodies, Monoclonal Antibodies, combinations of Monoclonal Antibodies, etc.) given to every infected individual within 72 hours of symptoms and diagnosis—over and over, again—thus, titrating to high titers in every infected individual commensurate to the antigens levels present in every infected individual.
2. Synergistic application with antivirals when available.

For survival of humanity long-term, the provision of vaccines as prophylaxis, ***Active Immunization***, should be administered throughout the World to all:

1. live homologous virus vaccines, e.g. vaccinia
2. attenuated live vaccines, e.g., Sabine polio vaccine
3. killed whole vaccines, e.g. Salk vaccine
4. mRNA vaccines, e.g. COVID-19 vaccines

So what are the tangible things that can be initiated upon completion of reading this paper?:

1. Much like the Flexner Report of over a century ago²⁵², U.S. Medicine must take a hard look at reinvigorating an analytical, Scientific-Mindset in its application throughout clinical Medicine
2. Every physician and surgeon should reflect and recommit to the absolute truism of the all clinicians of all ages²⁵⁵⁻²⁵⁶:

“... the secret of the care of the patient is in caring for the patient.”

3. As Anthony Fauci MD has stated that he has been a named editor of *Harrison's Principles of Internal Medicine*²⁵⁰ for 40 years¹⁸³ (11 times as a named editor and twice as the editor-in-chief), we should ask of him that he direct a major rewrite regarding how we teach the practice of medicine ongoing to all physicians who should be students of medicine for the rest of their lives—especially, in the treatment of viral diseases with exogenous immunoglobulins and antivirals (not just prophylaxis with vaccination). Consistent with a traditional full two-years in-depth study of the basic sciences in Medical School education in all U.S. Medical School, studies should be mandated with testing from hardcopy textbooks (not *de facto* electronic “cliff” notes and lectures) and then subsequent integration into the clinical years of medical school and residencies with

a mandatory internship-year in either Medicine (Internal and/or Pediatrics) or General Surgery.

4. As the M&M Conference is the legally protected, non-discoverable discussion venue under federal law, 38 U.S. Code § 5705, I would recommend that the President of the United States ask of the Secretary of the U.S. Department of Veterans Affairs to convene an M&M conference on the 10th floor of the VACO building across Lafayette Square from *The White House*.²⁵⁷⁻²⁵⁹ Such an M&M conference should be purposed to develop an outline throughout U.S. Medicine to better define adherence to Scientific Principles in daily Medical Clinical Practice. Such an M&M conference should include past and present members of the FDA, the NIAID, the NIH, the CDC, the US PHS, the VA (with the VHA USH or his/her designee leading the M&M conference); present and past editors of the *New England Journal of Medicine* and *JAMA*; and Doctors Joyner, Petroski, Casadevall, Henderson, etc. of the FDA/Mayo Clinic CCP protocol, etc. I would recommend a few surgeons be present who are well-versed and committed to the M&M conference—unfortunately, the one’s most appropriate in my eyes are all dead: C. Rollins Hanlon, MD, F.A.C.S., Vallee Willman, MD, F.A.C.S., C. Everett Koop, MD, F.A.C.S., J. Eugene Lewis, MD, F.A.C.S., C. Hiram Polk, MD, F.A.C.S., Frank E. Johnson, M.D., F.A.C.S., Claude H. Organ, Jr, MD, F.A.C.S., C. Hiram Polk, M.D., F.A.C.S., etc. While the living surgeon of today might not be as precise and focused as those Surgeon-educator-trailblazers, most assuredly, I could suggest some surgeon-educators whom I know personally that hold the importance of the M&M conference in the highest of regard. The topics to be discussed at such an M&M meeting(s) could come from the 72 index items on pages e-5 and e-6 of *Book 1—Dear Mr. President: COVID-19 and Where We Went Wrong*. <https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02>
<https://www.govinfo.gov/content/pkg/USCODE-2023-title38/pdf/USCODE-2023-title38-partIV-chap57-subchapI-sec5705.pdf>^{37,85,93}
5. While I have subscribed to *The New England Journal of Medicine* (NEJM)^{80,98,142,143} over most of my 47 years of medical education and practice and believe in the stated “integrity”⁸⁰ of the NEJM, this paper submission may be rejected by the editors of *The New England Journal of Medicine*. Regardless of what the editors of the NEJM decide, I will try to spread the news in whatever method will stimulate public awareness, e.g. uploading to the *Internet Archive*⁸⁷⁻⁸⁹; submitting it to the NIAID case #12276 Attachment IV for historical preservation within the U.S. Government, the FDA, the CDC, and the VA; writing the President of the United States, mailing it to members of Congress, etc. Personally, I see it as my duty as consistent with my commitment to the *Hippocratic Oath* as a Physician and Surgeon to stimulate the discussions and revisions of our concepts regarding COVID-19 that should follow from the distribution and dissemination of this draft paper wherever possible (even prior its possible publication in NEJM) to, e.g.: Medical Schools, Academia, the pharmaceutical industry, Government Health Agencies, and, figuratively speaking, every mall, every grocery store, every barber shop, and every street corner in America, etc.

On August 16, 2024, the NIH officially removed direct electronic access to the NIH COVID-19 Treatment Guidelines by removing the URL: <https://www.covid19treatmentguidelines.nih.gov/> from the Internet. Using the Wayback Machine, one could find that the guidelines were captured by the *Internet Archive* 4,983 times between April 21, 2020 and August 17, 2024: https://web.archive.org/web/20250000000000*/https://www.covid19treatmentguidelines.nih.gov/ As was stated in the *Annals of Internal Medicine* of November 2024²⁶⁰:

Development of treatment guidelines is not a typical role for the U.S. Department of Health and Human Service (HHS) and the National Institutes of Health (NIH); rather, such guidelines are usually developed by professional societies or the Centers for Disease and Prevention (CDC). However, given the NIH's long experience in creating HIV treatment guidelines, HHS requested that the NIH take the lead in expeditiously creating “**living**” treatment guidelines for COVID-19 that would be both widely accessible and frequently updated as important new information became available. This mandate posed special challenges in terms of obtaining sufficient time and attention from experts who were also responsible for their local institutional COVID-19-related clinical activities. Additional challenges included obtaining administrative support for coordinating operations, editing, and website management.

The NIH COVID-19 Treatment Guidelines (the Guidelines) were intended not as a mandate for clinicians or patients but as one source of credible expert advice that would evolve over time as additional data became available to inform therapeutic management strategies. The first release of the Guidelines was on 21 April 2020.

With the declaration of the end of the COVID-19 public health emergency (1,2), the NIH has determined it is now appropriate to sunset the NIH COVID-19 Treatment Guidelines. Drugs approved by the U.S. Food and Drug Administration (FDA) for treatment of COVID-19 are now available; outcomes for patients with COVID-19 are currently much better than in 2020 to 2022; and other organizations, such as the American College of Physicians, the Infectious Disease Society of America, the Pediatric Infectious Diseases Society, the World Health Organization, now provide readily accessible guidelines of their own (3-6).

The last update to the Guidelines (Supplement 1, available at *Annals.org*) was posted on 29 February 2024. All of the archived versions of the Guidelines from April 2020 to the last release are available at <https://wayback.archive-it.org/4887/20240626155844/https://www.covid19treatmentguidelines.nih.gov/> <https://www.covid19treatmentguidelines.nih.gov/> can thus only be found today through the *Wayback Machine of the Internet Archive*.]

For all of history, the U.S. National Institutes of Health (NIH) has figuratively, circuitously, electronically **discontinued the path to** their contributions to the guidelines they advanced during the American COVID-19 epidemic which, at the time, they claimed were “... ‘living’ treatment guidelines for COVID-19.” **Shame on the NIH** and shame on us all! I would allege, the NIH represents, in this case all of U.S. Medicine which essentially destroyed (or at least obfuscated) for all of history: the knowledge, the logic, the therapeutic intent, etc.--truths and errors--that were functionally driving our addressing of the American epidemic caused by the coronavirus, SARS-Cov-2, COVID-19, that confronted the people of the United States of America from 2020 to the present day--and, is still endemically, ongoing!

Over the four-year interval to the last publication of the *NIH COVID-19 Treatment Guidelines* of February 29, 2024 (and subsequent discontinuation of the URL by the NIH on <https://www.covid19treatmentguidelines.nih.gov/> of August 16, 2024²⁶⁰):

The Guidelines consisted of 90 pages in the first iteration, 278 pages at the end of 12 months, and 478 pages in the last edition. Forty pages were archived when their contents were deemed to no longer be

relevant for clinicians. From 21 April 2020 until the final update on 29 February 2024, the Panel voted on recommendations 438 times (Table 5 of **Supplement 2**).

In total, there were 71 updates of the Guidelines from April 2020 through February 2024. As shown in **Figure 1**, updates, rapid communications, and revisions were initially frequent and then slowed in 2023 and 2024. These were generally driven by the release of data from clinical trials, information from other publications that was important to therapeutic management, or announcements from the FDA.

From the beginning of the pandemic through February 2024, the FDA issued 17 emergency use authorizations (EUAs) for COVID-19-related drugs. Of these 17 EUAs, 4 of the drugs (hydroxychloroquine, COVID-19 convalescent plasma, anakinra, and vilobelimab) were not recommended for use by the Panel. **Figure 2** shows the timing of FDA actions for preventive and therapeutic products related to management of COVID-19 from March 2020 to February 2024.

As of 29 February 2024, the Guidelines had received more than 50 million page views from more than 26 million users. The number of unique users (**Figure 3**) and page views closely followed the curve of pandemic hospitalizations in the United States. Unpredictable surges in caseloads highlighted the importance of keeping the recommendations current. Although most page views were from the United States, approximately 20% to 25% were from other countries, notably Australia, Canada, India, Japan, Malaysia, Mexico, and Thailand.

The sunseting by electronic overwriting and paltering iterations of *NIH COVID-19 Treatment Guideline*²⁶⁰ has been tantamount to the destruction of the 72 URLs of the *NIH COVID-19 Treatment Guidelines* akin to a Nazi book burning²⁶¹ but stealthily in American society today. Such electronic sunseting may be dutifully an electronic preservation of all 72 iterations on the computerized server farm of the *Internet Archive*--a non-governmental, non-profit 501(c)(3) institution⁸⁷⁻⁸⁹; but in reality, though, the electronic sunseting of medical history is subtly obfuscative; intricately, minimally discoverable; and surreptitiously destructive of human knowledge. I would allege that as the NIH is an agency of the U.S. Department of Health and Human Services (DHHS), the electronic sunseting of the *NIH COVID-19 Treatment Guidelines* is a violation of the intent of the Sarbanes-Oxley Act of 2002, 18 U.S.C. §15129(c)(1).¹⁰³ Such electronic-storage-only is unintellectually and unethically suppressive by the *de facto* failure to the preserve tangibly in an accessible hardcopy format for future generations the trials and tribulations and accomplishments and mistakes in our society's most-recent attempts at the advancement of human knowledge regarding COVID-19. Instead of disguising the 72 iterations of the NIH COVID-19 Treatment Guidelines²⁶⁰ from future medical practitioners, every hospital and medical school library in the U.S.A. should printout all 72 iterations and shelve them as a medical series physically in their tangible Reference sections, e.g.: Using a computer and a color laser printer, one can printout each iteration from the *Internet Archive*⁸⁷⁻⁸⁹ for inclusion in such a medical reference series with just a half-a-ream of paper, 4 printer cartridges, binding materials, and approximately 15 minutes of computer printer time and human effort (72 iterations x ¼ hour = 18 man-hours /library).—that, to me, seems like a bargain in the preservation of the present medical thought process for all of history.

So, as coronavirus, SARS-Cov-2, COVID-19 is an endemically ongoing scourge of man, why have we electronically misplaced the 72 interactions—correct or incorrect--of the NIH COVID-19 Treatment Guidelines? All of us in U.S. Medicine have the ethical responsibility to sort out the truth in Medicine. We are ethically mandated by our profession to explain to the American people in a clear and concise manner the applicability of the medical doctrine in their individual daily lives and individual medical care. Early-on in the American COVID-19 epidemic, this was pointed out to the American people--so *apropos* on April 1, 2020, April Fools' Day--in an interview of Dr. Fauci by Norah O'Donnell on the CBS Nightly News²⁶²:

Norah O'Donnell: With all due respect it does seem like so much of this we're making it up as we go along.

Dr. Anthony Fauci: Well, you know you make it up as you go along, Norah, because that's what you know—that's where the war is all about. I don't like to necessarily make that analogy to a war, but if you talk to the generals with experience, you have a plan. But when the bullets start flying, everything becomes a fog, and you have to play it by ear. We do have a good plan. We need to be humble that we don't know all the answers, and we don't know how exactly this is going to turn out.

Norah O'Donnell: Dr. Fauci, thank you so very much for your time and expertise.

Dr. Anthony Fauci: It's always good to be with you, Norah. Thank you.

O'Donnell N: BREAKING NEWS: Dr. Fauci on the fight against the virus.
<https://www.facebook.com/CBSEveningNews/videos/norah-odonnell-should-we-be-advising-people-to-wear-masksdr-anthony-fauci-great-/204826050813336/> 2020 April 1, 2:10 – 2:48

In the fight against the American COVID-19 epidemic, as physicians and surgeons of U.S. Medicine, did we really live up to Francis W. Peabody's admonition 100 years ago emphasizing our basic underlying moral promise to humanity as individual physicians towards each and every unique, individual patient that presents to us?--For:

"...the secret of the care of the patient is in caring for the patient."^{255,256}

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.

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1.) Nobody defined the foundational basics of Clinical Immunology: Active Immunization and Passive Immunization.

2.) Everything was in Generalities – NOT THE INDIVIDUAL PATIENT!

3.) The not-for-profit American Red Cross was *NOT* officially invited “to the table” until July 30, 2020—by that time, the U.S.A. had gone so far down the Rabbit Hole, they did not know how to get out!

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The people of the United States of America and the World owe a tremendous debt of gratitude to *Elsevier* for their unselfish gesture for the betterment to humanity in its time of need:

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19 related research that is available on the COVID-19 resource centre – including this research content – immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

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Antibodies have been used for a century for the prevention and treatment of infectious diseases (Table 1). In bacterial disease, antibodies neutralize toxins, facilitate opsonization, and, with complement, promote bacteriolysis; in viral disease, antibodies block viral entry into uninfected cells, promote antibody-directed cell-mediated cytotoxicity by natural killer cells, and neutralize virus alone or with the participation of complement.

Prior to the use of antibiotics, antibodies were the only specific agents for the treatment of certain infections. Although this role has largely been supplanted by antibiotics, there still remains a crucial role for antibody in the treatment of certain infectious diseases (Table 1). Since several excellent reviews are available, this article will emphasize new developments (30, 31, 101, 164, 165).

Antibodies can be administered as human or animal plasma or serum, as pooled human immunoglobulin for intravenous (IVIG) or intramuscular (IG) use, as high-titer human IVIG or IG from immunized or convalescing donors, and as monoclonal antibodies (Mab) (30, 164, 178). The therapeutic use of Mab is increasing dramatically, but only one (palivizumab for respiratory syncytial virus [RSV]) has been licensed for prophylaxis of an infectious disease.

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January 26, 2022: <https://web.archive.org/web/20220126211035/https://www.nejm.org/media-center/integrity-safeguards>
April 27, 2022: <https://web.archive.org/web/20220427010009/https://www.nejm.org/media-center/integrity-safeguards>
August 2, 2022: <https://web.archive.org/web/20220802123717/https://www.nejm.org/media-center/integrity-safeguards>

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<https://web.archive.org/web/20220808070959/https://www.nejm.org/media-center/integrity-safeguards>

August 19, 2022: <https://web.archive.org/web/20220819092753/https://www.nejm.org/media-center/integrity-safeguards>

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November 2, 2022:

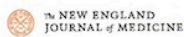
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April 10, 2023:

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Integrity Safeguards

Integrity Safeguards



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- Since 1984, has requested author disclosures, and pioneered in 2009, with the International Committee of Medical Journal Editors (ICMJE), a [universal disclosure form](#) that requests that authors report all relevant financial conflicts during the 36 months before publication.
- Took the lead among medical journals in 2011 to publish study protocols with all randomized, controlled trials. NEJM is still one of the few general medical journals that publishes protocols with all randomized trials.
- Broke new ground, along with the ICMJE, in requiring sharing of clinical trial data. As of 2018, NEJM required authors to include a data sharing statement when submitting an article for publication. In 2019, they were required to enter a data sharing plan in the trial's registration.

Beyond promoting clinical trial registration and ICMJE universal standard disclosure for all scientific medical reporting, NEJM:

- Works diligently to ensure that research conclusions are neither overstated nor misleading, that results are placed in proper context for clinical practice, and that peer review informs editorial decisions.
- Grants immediate free access to low-income countries through partnership with Reasearch4Life's [Access to Research in Health](#) (Hinari) program.
- Enforces strict rules around disclosure of paper authorship.
- Carefully reviews manuscript, protocol, and trial registrations of every randomized clinical trial.
- Maintains strict separation between editorial and business considerations.

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http://web.archive.org/web/20161221045318/https://www.va.gov/oaa/1400_1hk_Oct2001.doc*, one can find the 2001 version in the 2004 of the Internet Archive captures. There are no other captures of this URL in the Wayback Machine except December 21, 2016 which brings up the VA Website which states: “Page Not Found.”*
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Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts.

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https://web.archive.org/web/20230722070741/https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2958 In **2. SUMMARY OF CHANGES** of the **Transmittal Sheet** which is still labelled **December 24, 2013** but in red has stamped: **AMENDED May 17, 2022** is: (1) Paragraphs 2.c. and 2.e. removes references to the Supremacy Clause reference and physician liability.—which means that the independent practice of a VHA Physician Assistant was rescinded returning all Physicians Assistants to the State Medical Board statutes outlining mandatory Physician scope of practice affiliations and legally mandated Physician oversight. The signatory official on this document is Robert A. Petzel, M.D., Under Secretary for Health who had been terminated over the Phoenix VAMC scandal 8 years prior to this as noted above in references 36 and 37.
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[file:///Users/andrusmd1/Downloads/1063\(2\)_D_2013-12-24%20\(6\).pdf](file:///Users/andrusmd1/Downloads/1063(2)_D_2013-12-24%20(6).pdf). The <https://...> URL version was captured by the *Internet Archive* on July 18, 2024. The signatory official on this document is still Robert A. Petzel, M.D., Under Secretary for Health, who had been terminated over the Phoenix VAMC scandal 10 years prior to this as noted above in references 36 and 37.
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After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired *Fighting for Care* narrated by Diane Sawyer. 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Temple, TX VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, *ABC News PrimeTime Live*, for "Fighting for Care," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents– I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Temple TX VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

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 144. Pardo J, Shukia AM, Chamarthi G, Gupte A: The journey of remdesivir: from Ebola and COVID-19. *Drugs in Context* 2020 Apr 14; 9: 1-9
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7250494/pdf/dic-2020-4-14.pdf>
 145. Gottlieb S: Former FDA chief Gottlieb explains the potential of Gilead's Covid-19 treatment. (The Antiviral Remdesivir)
<https://www.cnn.com/video/2020/04/17/gottlieb-treatment-gilead-clinical-trials-covid-19-squawk-box.html>
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 148. Lovelace B: Dr. Anthony Fauci says Gilead's remdesivir will set a new 'standard of care' for coronavirus treatment. *CNBC*. <https://www.cnn.com/2020/04/29/dr-anthony-fauci-says-data-from-remdesivir-coronavirus-drug-trial-shows-quite-good-news.html>
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151. Humeniuk R, Mathias A, Cao H, Osinusi A, Shen G, Chng E, Ling J, Vu A, German P: Safety, tolerability, and pharmacokinetics of Remdesivir, An antiviral for treatment of COVID-19, in healthy subjects. Clin Transl Sci 2020; 13: 896 - 906.
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152. McEnany K: White House Press Conference, June 19, 2020.
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...Finally, well second, to finally, we are encouraged that we continue to gather positive data on a number of therapeutics: heparin; dexamethasone or steroids as it's more commonly known; convalescent plasma; and Remdesivir have all shown promise in treating coronavirus. Preliminary findings in a large UK-based recovery trial found that when steroids were used there was a 30% reduction in death for coronavirus patients on ventilators. The FDA is reviewing this recovery trial data now. Additionally, on convalescent plasma there's more encouraging news in partnership with mayo clinic the Trump administration move very quickly on this therapy and it's earliest days recognizing that it showed promise. Through the FDA Mayo Clinic and the administration's work in our hand-in-hand partnership, we found that this treatment is very promising--this has shown that the administration has left no stone unturned in looking at every possible treatment at the very early stages. The lead investigator of this Mayo Clinic study, Dr. Michael Joyner, summed up his work in saying that convalescent plasma "continues to look promising" noting the "excellent news of this study which covered a diverse population of patients about 20% were African-American, nearly 35% Hispanic, 5% Asian, and 40% women. Prior experience with respiratory viruses and some data that have emerged globally suggest convalescent plasma has the potential to lessen the severity or shorten the length of the illness caused by COVID-19. The results from the Mayo underscore that promise. As you can see, the Trump administration and FDA led on identifying convalescent plasma as a therapeutic and the results are encouraging...

153. Hinton D, FDA Chief Scientist: U.S. Food & Drug Administration Emergency Use Authorization (EUA) regarding Remdesivir. Letter from RADM Hinton to Ms Rhoades, Gilead Sciences, Inc.
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Pages 1 – 2:

On May 1, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Veklury (remdesivir)³ for the treatment of hospitalized patients with severe 2019 coronavirus disease (COVID-19)⁴, pursuant to Section 564 of the Act. Veklury is a direct acting antiviral drug that inhibits viral RNA synthesis. It is an investigational drug and is not currently approved for any indication.

On August 28, 2020, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the May 1, 2020 letter in its entirety with revisions incorporated to expand the authorized use of Veklury by no longer limiting its use to the treatment of patients with severe disease. In addition, the Fact Sheet for Health Care Providers has been revised to provide updated clinical trial results and supporting data.⁵ ***(VERY IMPORTANT: This negative statement: "...by no longer limiting its use to the treatment of patients with severe disease..." is obfuscation by the FDA. The positive statement that the FDA failed to state at the time and FDA has never stated is: Veklury (Remdesivir) is indicated most efficaciously in the early treatment of COVID-***

19 in the viremic phase (best within 72 hours of diagnosis) because it inhibits RNA polymerase replication of the COVID-19 RNA. The justifying REASON for this is: “The active form of remdesivir acts as a nucleoside analog and inhibits the RNA-dependent RNA polymerase (RdRp) of coronaviruses including SARS-CoV-2. Remdesivir is incorporated by the RdRp into the growing RNA product and allows for addition of three more nucleotides before RNA synthesis stalls. ...” Kokic G, Hillen HS, Tegunov D, Dienemann C, Seitz F, Schmitzova J, Farnung L, Siewert A, Hobartner C, Cramer P: Mechanism of SARS-CoV-2 polymerase stalling by remdesivir. *Nature Communications* (2021)12:279 <https://doi.org/10.1038/s41467-020-20542-0>
<https://www.nature.com/articles/s41467-020-20542-0.pdf>

¹ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. February 4, 2020.

² U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

³ The May 1, 2020 EUA referred to the authorized drug as “remdesivir;” however, Gilead subsequently requested, and FDA concurred, that the Fact Sheets be altered to add references to remdesivir’s trade name, “Veklury.” “Veklury” is used in this August 28, 2020 reissued letter.

⁴ For purposes of the May 1, 2020 EUA, patients with severe disease were defined as patients with oxygen saturation $\leq 94\%$ on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO).

⁵ Prior to this reissuance and pursuant to the conditions of authorization, Gilead had requested, and FDA had concurred with other changes to the Fact Sheets, including but not limited to: (1) clarified dosing and administration

Pages 2-3:

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

Distribution of the authorized Veklury will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA

Gilead will supply Veklury to authorized distributors⁷, or directly to a U.S. government agency, who will distribute to hospitals and other healthcare facilities as directed by the U.S. Government, in collaboration with state and local government authorities, as needed;

The Veklury covered by this authorization will be used only to treat adults and children with suspected or laboratory confirmed COVID-19 administered in an in-patient hospital setting via intravenous (IV) infusion by a healthcare provider; and

The use of Veklury covered by this authorization should be in accordance with the dosing regimens as detailed in the authorized Facts Sheets.

154. Philpiddis A, LeMieux J: Trump's treatments: Regeneron's antibodies and Gilead's Remdesivir explained. Genetic Engineering & Biotechnology News.
<https://www.genengnews.com/insights/trumps-treatments-regenerons-antibodies-and-gileads-remdesivir-explained/>
155. Beigel JH, Tomashek KM, Dodd LE, Mehta AK, Zingman BS, Kalil A, Hohmann E, Chu HY, Luetkemeyer A, Kline S, Lopez de Castilla D, Finberg RW, Dierberg K, Tapson V, Hsieh L, Patterson TF, Paredes R, Sweeney DA, Short WR, Touloumi G, Lye DC, Ohmagari N, Oh Myoung-don, Ruiz-Palacios GM, Benfield T, Fatkenheuer G, Kortepeter MG, Atmar RL, Creech CB, Lundgren J, Babiker AG, Pett S, Neaton JD, Bergess TH, Bonnett T, Green M, Makowski M, Osinusi A, Nayak S, Lane HC, for the ACTT-1 Study Group Members. Remdesivir for the treatment of Covid-19 – Final Report. NEJM.org, October 8, 2020. Published in harcopy N Engl J Med 2020; 383:1813-1826. November 5, 2020. A preliminary version of this article was published on May 22, 2020. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2007764>

SAFETY OUTCOMES

In the as-treated population, serious adverse events occurred in 131 of 532 patients (24.6%) in the remdesivir group and in 163 of 516 patients (31.6%) in the placebo group (Table S17). There were 47 serious respiratory failure adverse events in the remdesivir group (8.8% of patients), including acute respiratory failure and the need for endotracheal intubation, and 80 in the placebo group (15.5% of patients) (Table S19). No deaths were considered by the investigators to be related to treatment assignment.

Grade 3 or 4 adverse events occurred on or before day 29 in 273 patients (51.3%) in the remdesivir group and in 295 (57.2%) in the placebo group (Table S18); 41 events were judged by the investigators to be related to remdesivir and 47 events to placebo (Table S17). The most common nonserious adverse events occurring in at least 5% of all patients included decreased glomerular filtration rate, decreased hemoglobin level, decreased lymphocyte count, respiratory failure, anemia, pyrexia, hyperglycemia, increased blood creatinine level, and increased blood glucose level (Table S20). The incidence of these adverse events was generally similar in the remdesivir and placebo groups.

Given the preliminary results about remdesivir, the Food and Drug Administration issued an Emergency Use Authorization on May 1, 2020 (modified on August 28, 2020), to permit the use of remdesivir for treatment in adults and children hospitalized with suspected or laboratory-confirmed Covid-19. Remdesivir has also received full or conditional approval in several other countries since that time. However, given high mortality despite the use of remdesivir, it is clear that treatment with an antiviral drug alone is not likely to be sufficient for all patients. Current strategies are evaluating remdesivir in combination with modifiers of the immune response (e.g., the Janus kinase [JAK] inhibitor baricitinib in ACTT-2, and interferon beta-1a in ACTT-3). A variety of therapeutic approaches including novel antivirals, modifiers of the immune response or other intrinsic pathways, and combination approaches are needed to continue to improve outcomes in patients with Covid-19.

156. Farley JJ, Director, Office of Infectious Diseases, U.S. Food & Drug Administration: FDA New Drug Approval for Remdesivir **NDA 214787**. Letter from John Farley, MD, MPH to Ms Rhoades, Gilead Sciences, Inc. authorizing a **New Drug Authorization Approval** 2020 October 22

https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf

NDA APPROVAL 214787

Gilead Sciences, Inc.
Attention: Ashley Rhoades, MBS, RAC
Manager, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Rhoades:

Please refer to your new drug application (NDA) dated and received August 7, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VEKLURY (remdesivir) injection, 5 mg/mL; VEKLURY (remdesivir) for injection, 100 mg/vial.

This new drug application provides for the use of VEKLURY (remdesivir) injection, and VEKLURY (remdesivir) for injection, for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) **for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization.** VEKLURY should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

157. Rubin D, Chan-Tack K, Farley J, Sherwat A: FDA approval of remdesivir—A step in the right direction. N Engl J Med 2020 December 31; 383: 2598-2600.
<https://www.nejm.org/doi/pdf/10.1056/NEJMp2032369>
158. Downs Burger J: Novel coronavirus: EMTALA compliance for hospitals with dedicated emergency departments. Arnall, Golden, Gregory LLP 2020 March 09
<https://www.agg.com/news-insights/publications/novel-coronavirus-emtala-compliance-for-hospitals-with-dedicated-emergency-departments-2/>
159. Azar AM: Waiver or modification of requirements under section 1135 of the Social Security Act. 2020 March 13.
www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx previous has been taken off the web; therefore using the Wayback Machine, there are 162 captures of which this is the March 16, 2020 capture:
<https://web.archive.org/web/20200316224950/www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>
160. Bruce JM, Mitchell JO: HHS waives certain EMTALA requirements, Medicare conditions of participation, and HIPAA sanctions during the COVID-19 Pandemic. The National Law Review 2022 March 25; XII (84): 1-7.
<https://www.natlawreview.com/article/hhs-waives-certain-emtala-requirements-medicare-conditions-participation-and-hipaa>
161. ACEP COVID-19 Field Guide: EMTALA Regulations and Liability.
<https://www.acep.org/corona/covid-19-field-guide/regulations-and-liability/emtala/>

- which can no longer be found on the Internet but using the Wayback Machine, 20 captures are noted with the first capture being August 6, 2020.
<https://web.archive.org/web/20200806015843/https://www.acep.org/corona/covid-19-field-guide/regulations-and-liability/emtala/>
162. President Trump signed into law PL-115-176: Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina, the RIGHT TO TRY ACT OF 2017. 2018 May 30 <https://www.govinfo.gov/content/pkg/PLAW-115publ176/pdf/PLAW-115publ176.pdf>
 163. Agarwal R, Saltz LB: Understanding the Right to Try Act. Clin Cancer Res. 2020 Jan 15; 26(2): 340-343. (HHS Public Access Author manuscript, Clin Cancer Res. Author manuscript; available in PMC 2020 August 10. Nihms-1541631.pdf <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7416898/>).
<https://pmc.ncbi.nlm.nih.gov/articles/PMC7416898/pdf/nihms-1541631.pdf>
 164. Trump D: Donald Trump August 23 White House COVID-19 Press Conference Transcript. Rev Aug 23, 2020. Video of the conference:
<https://www.youtube.com/watch?v=nE0EkrElCRk> Transcript:
<https://www.rev.com/blog/transcripts/donald-trump-august-23-white-house-covid-19-press-conference-transcript> which can no longer be found on the Internet but using the Wayback Machine, 12 captures are noted with the first capture being September 1, 2020.
 165. Andrus CH: Re: Thousands of Americans are *needless dying* because the FDA is illegally ignoring PL 115-176 – The *Right to Try Law* and COVID-19 Convalescent Plasma has NOT been given as Prophylaxis and Early after COVID-19 positivity conversion. **Letter mailed to President Trump and the offices of the U.S. Senate.**
0.8 Attachment VII Letters to Members of Congress and Pres Trump 8_23_2020 and 8_28_2020
<https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02/page/993/mode/1up?q=Members+of+Congress&view=theater>
 166. FDA News Release: FDA issues emergency use authorization for Convalescent Plasma as potential promising COVID-19 treatment, another achievement in Administration’s fight against pandemic. U.S. Food & Drug Administration.
<https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients as part of the agency’s ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its [decision memorandum](#), this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product.

Today’s action follows the FDA’s extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing.
The EUA authorizes the distribution of COVID-19 convalescent plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with COVID-19.

Alex Azar, Health and Human Services Secretary:

“The FDA’s emergency authorization for convalescent plasma is a milestone achievement in President Trump’s efforts to save lives from COVID-19,” said Secretary Azar. “The Trump Administration recognized the potential of convalescent plasma early on. Months ago, the FDA, BARDA, and private partners began work on making this product available across the country while continuing to evaluate data through clinical trials. Our work on convalescent plasma has delivered broader access to the product than is available in any other country and reached more than 70,000 American patients so far. We are deeply grateful to Americans who have already donated and encourage individuals who have recovered from COVID-19 to consider donating convalescent plasma.”

Stephen M. Hahn, M.D., FDA Commissioner:

“I am committed to releasing safe and potentially helpful treatments for COVID-19 as quickly as possible in order to save lives. We’re encouraged by the early promising data that we’ve seen about convalescent plasma. The data from studies conducted this year shows that plasma from patients who’ve recovered from COVID-19 has the potential to help treat those who are suffering from the effects of getting this terrible virus,” said Dr. Hahn. “At the same time, we will continue to work with researchers to continue randomized clinical trials to study the safety and effectiveness of convalescent plasma in treating patients infected with the novel coronavirus.”

Scientific Evidence on Convalescent Plasma

Based on an evaluation of the [EUA criteria](#) and the totality of the available scientific evidence, the FDA’s Center for Biologics Evaluation and Research determined that the statutory criteria for issuing an EUA criteria were met.

The FDA determined that it is reasonable to believe that COVID-19 convalescent plasma may be effective in lessening the severity or shortening the length of COVID-19 illness in some hospitalized patients. The agency also determined that the known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product and that there are no adequate, approved, and available alternative treatments.

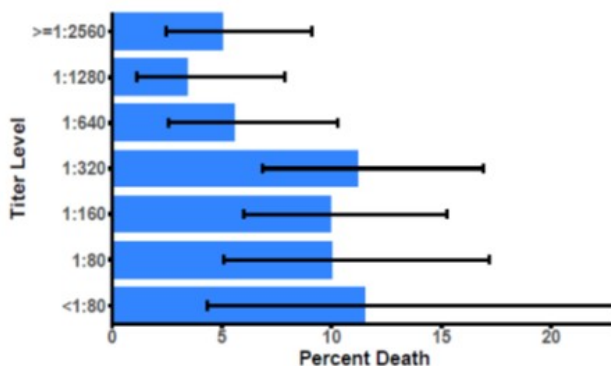
The EUA is not intended to replace randomized clinical trials and facilitating the enrollment of patients into any of the ongoing randomized clinical trials is critically important for the definitive demonstration of safety and efficacy of COVID-19 convalescent plasma. The FDA continues to recommend that the designs of ongoing randomized clinical trials of COVID-19 convalescent plasma and other therapeutic agents remain unaltered, as COVID-19 convalescent plasma does not yet represent a new standard of care based on the current available evidence.

The EUA remains in effect until the termination of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19. The EUA may be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance.

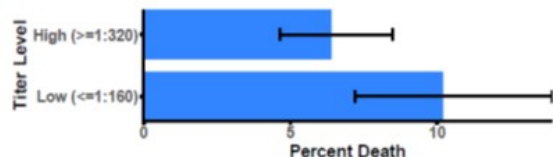
COVID-19 Convalescent Plasma Reduction in Death at 7 Days



Non-intubated patients treated
within 72 h age 80 or less (n=1018)



Statistically significant 37% reduction
in mortality in those treated with high
titer convalescent plasma (p=.03)



High titer corresponds
approximately to Ortho
VITROS S/C level ≥ 12

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products

167. FDA: Updated Evidence to Support the Emergency Use of COVID-19 Convalescent Plasma – as of 9/23/2020. <https://www.fda.gov/media/142386/download>

Table 1. 7- and 28-Day Deaths in Patients Treated with COVID-19 Convalescent Plasma

	7-day			28-day		
	Overall (N=4330)	Not Intub (N=2488)	Not intub, ≤80 y, ≤72 h (N=932)	Overall (N=2817)	Not Intub (N=1238)	Not intub, ≤80 y, ≤72 h (N=485)
Deaths Lower Titer	14.97%	13.99%	11.29%	49.57%	49.43%	46.63%
Deaths Higher Titer	13.61%	11.00%	6.27%	46.21%	41.48%	33.23%
Absolute Improvement	1.36%	2.99%	5.02%	3.36%	7.95%	13.40%
Relative Improvement	9%	21%	44%	7%	16%	29%
Statistical Significance	Not significant	Significant p=0.03	Significant p=0.008	Not significant	Significant p=0.004	Significant p=0.004

168. 2020-04-07 Bloch EM, Shoham S, Casadevall A, Sachals BS, Shaz B, Winters JL, van Buskirk C, Grossman BJ, Joyner M, Henderson JR, A, Lau B, Wesolowski A, Katz L, Shan H, Auwaerter PG, Thomas D, Sullivan DJ, Paneth N, Gehrie E, Spitalnik S, Hod EA, Pollack L, Nicholson WT, Pirofski L, Bailey JA, Tobian AAR: Deployment of convalescent plasma for the prevention and treatment of COVID-19. <https://www.jci.org/articles/view/138745> or .pdf version: <https://www.jci.org/articles/view/138745/pdf>
169. 2020-05-14 Joyner MJ, Wright RS, Fairweather D, Senefeld JW, Bruno KA, Klassen SA, Carter RE, Klompas AM, Wiggins CC, Shepherd JRA, Rea RF, Whelan ER, Clayburn AJ, Spiegel MR, Johnson PW, Lesser ER, Baker SE, Larson KF, Ripoll JG, Andersen KJ, Hodge DO, Kunze KL, Buras MR, Vogt MNP, Herasevich V, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Buskirk CMV, Winters JL, Stubbs JR, Paneth NS, Casadevall A: Early safety indicators of COVID-19 convalescent plasma in 5,000 patients. MedRxiv – Preprint May 12, 2020. <https://web.archive.org/web/20200515045004/https://www.medrxiv.org/content/10.1101/2020.05.12.20099879v1.full.pdf>
170. 2020-06-03 Casadevall A, Joyner MJ, Pirofski LA: A randomized trial of convalescent plasma for COVID-19 -- Potentially hopeful signals. JAMA. June 3, 2020: E1 – E3. <https://pubmed.ncbi.nlm.nih.gov/32492105/>; August 4, 2020; 324 (5): 455-457. <https://jamanetwork.com/journals/jama/fullarticle/2766940>
171. 2020-07-07 Casadevall A, Joyner MJ, Pirofski LA: SARS-CoV-2 viral load and antibody responses: the case for convalescent plasma therapy. J Clinical Investigation 2020 Jul 7; 130 (10): 5112-5114. <https://www.jci.org/articles/view/139760/pdf>
172. 2020-07-19 Joyner MJ, Bruno KA, Klassen SA, Kunze KL, Johnson PW, Lesser ER, Wiggins CC, Senefeld JW, Klompas AM, Hodge DO, Shepherd JRA, Rea RF,

- Whelan ER, Clayburn AJ, Spiegel MR, Baker SE, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Herasevich V, Dennis JJ, Regimabal RJ, Bauer PR, Blair JE, van Buskirk CM, Winters JL, Stubbs JR, van Helmond N, Butterfield BP, Sexton MA, Soto JCD, Paneth NS, Verdun NC, Marks P, Casadevall A, Fairweather D, Carter RE, Wright RS. COVID-19 Convalescent Plasma in 20,000 hospitalized patients. *Mayo Clin Proc* September 2020; 95(9): 1888-1897.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7368917/pdf/main.pdf>
173. 2020-08-12 Joyner MJ, Senefeld JW, Klassen SA, Mills JR, Johnson PW, Theel ES, Wiggins CC, Bruno KA, Klompas AM, Lesser ER, Kunze KL, Sexton MA, Soto JCD, Baker SE, Shepherd JRA, van Helmond N, van Buskirk CM, Winters JL, Stubbs JR, Rea RF, Hodge DO, Herasevich V, Whelan ER, Clayburn AJ, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Paneth NS, Fairweather DL, Wright RS, Carter RE, Casadevall A: Effect of convalescent plasma on mortality among hospitalized patients with COVID-19: Initial three-month experience. Version 1. medRxiv Preprint. 2020 Aug 12.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7430623/?report=printable>
 174. 2021-01-13 Joyner MJ, Carter RE, Senefeld JW, Klassen SA, Mills JR, Johnson PW, Theel ES, Wiggins CC, Bruno KA, Klompas AM, Lesser ER, Kunze KL, Sexton MA, Diaz Soto JC, Baker SE, Shepherd JRA, van Helmond N, Verdun NC, Marks P, van Buskirk CM, Winters JL, Stubbs JR, Rea FR, Hodge DO, Herasevich V, Whelan ER, Clayburn AJ, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Paneth NS, Fairweather D, Wright RS, Casadevall A, *et. al.*: Convalescent plasma antibody levels and the risk of death from Covid-19. *N Engl J Med*, January 13, 2021, at NEJM.org; then republished *N Engl J Med* 2021; 384:1015-1027. <https://www.nejm.org/doi/full/10.1056/NEJMoa2031893>
 175. 2021-03-18 Joyner MJ, Carter RE, Senefeld JW, Klassen SA, Mills JR, Johnson PW, Theel ES, Wiggins CC, Bruno KA, Klompas AM, Lesser ER, Kunze KL, Sexton MA, Diaz Soto JC, Baker SE, Shepherd JRA, van Helmond N, Verdun NC, Marks P, van Buskirk CM, Winters JL, Stubbs JR, Rea RF, Hodge DO, Herasevich V, Whelan ER, Clayburn AJ, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Paneth NS, Fairweather DL: Wright RS, Casadevall A: Convalescent plasma antibody levels and the risk of death from Covid-19. *N Engl J Med* 2021 Mar 18; 384 (11):
<https://www.nejm.org/doi/full/10.1056/nejmoa2031893> and
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2031893?articleTools=true>
 176. 2021-05 Klassen SA, Senefeld JW, Johnson PW, Carter RE, Wiggins CC, Shoham S, Grossman BJ, Henderson JP, Musser J, Salazar E, Hartman WR, Bouvier NM, Liu STH, Pirofski LA, Baker SE, van Helmond N, Wright TS, Fairweather D, Bruno KA, Wang Z, Paneth NS, Casadevall A, Joyner M: The effect of convalescent plasma therapy on COVID-19 patient mortality: Systematic review and meta-analysis. *Mayo Clin Proc*, 2021 May; 96 (5): 1262-1275.
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... Importantly, many of the patients enrolled in the studies included in the analyses received convalescent plasma transfusions later in their disease course. In this context, before antibiotics and effective vaccinations, convalescent plasma therapy was widely understood to be most efficacious very early in the course of hospitalizations.² · 155 As a result, our analysis may underestimate the mortality reduction achievable through early administration of high-titer convalescent plasma for COVID-19.

Conclusion

This real-time systematic review and meta-analysis of contemporaneous studies highlights that the mortality rate of transfused patients with COVID-19 was lower than that of nontransfused patients with COVID-19 and suggests that **early transfusion of high-titer plasma represents the optimal use scenario to reduce the risk of mortality among patients with COVID-19**. These results favor the efficacy of convalescent plasma as a COVID-19 therapeutic agent.

177. 2021-06-04 Casadevall A, Dragotakes Q, Johnson PW, Senefeld JW, Klassen SA, Wright RS, Joyner MJ, Paneth N, Carter RE: Convalescent plasma use in the USA was inversely correlated with COVID-19 mortality. eLife 2021; 10e69866. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8205484/pdf/elife-69866.pdf>

Abstract: *(Extremely Important!)*

...Changes in the number of hospital admissions, SARS-CoV-2 variants, and age of patients could not explain these findings. The retreat from CCP might have resulted in as many as 29,000 excess deaths from mid-November 2020 to February 2021.

Conclusions: A strong inverse correlation between CCP use and mortality per admission in the USA provides population-level evidence consistent with the notion that CCP reduces mortality in COVID-19 and suggests that the recent decline in usage could have resulted in excess deaths.

178. 2021-12-20 Senefeld JW, Johnson PW, Kunze KL, Bloch EM, van Helmond N, Golafshar MA, Klassen SA, Klompas AM, Sexton MA, Diaz Soto JC, Grossman BJ, Tobian AAR, Goel R, Wiggins JL, Casadevall A, Paneth NS, Shaz BH, Petersen MM, Sachais BS, Buras MR, Wiecek MA, Russoniello B, Dumont LJ, Baker SE, Vassallo RR, Shepherd JRA, Young PP, Verdun NC, Marks P, Haley NR, Rea RF, Katz L, Herasevich V, Waxman DA, Whelan ER, Bergman A, Clayburn AJ, Grabowski MK, Larson KF, Ripoll JG, Andersen KJ, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Buchholtz ZA, Pletsch MC, Wright K, Greenshields JT, Joyner MJ, Wright RS, Carter RE, Fairweather D: Access to and safety of COVID-19 convalescent plasma in the United States Expanded Access Program: A national registry study. PLOS Medicine 2021 December 20. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8730442/pdf/pmed.1003872.pdf>
179. 2022-02 Paneth N, Casadevall A, Pirofski L, Henderson JP, Grossman BJ, Shoham S, Joyner MJ: WHO covid-19 drugs guideline: reconsider using convalescent plasma. BMJ 2022 February; 376: o295. <https://www.bmj.com/content/376/bmj.o295>
180. 2022-03-07 Casadevall A, Grossman BJ, Joyner MJ, Henderson JP, Paneth N, Pirofski LA, Shoham S: National COVID-19 Convalescent Plasma Project. Last digitized for International Archive, March 7, 2022.

- <https://ccpp19.org/about/index.html> which can no longer be found on the Internet but using the Wayback Machine, 152 captures are noted with the first capture being April 1, 2020.
181. Villa CH to Verdun N: Regarding EUA 26382. U.S. Food & Drug Administration, undated in February 2021, this URL of 2/5/2021, <https://www.fda.gov/media/141480/download> is the URL representing the overwritten version of the August 23, 2020 (version: <https://web.archive.org/web/20200823223716/https://www.fda.gov/media/141480/download>). So as to preserve for history the present version of February 5, 2021, first Internet Archive capture of February 15, 2021 is: <https://web.archive.org/web/20210215192634/https://www.fda.gov/media/141480/download>
 182. Villa CH, Medical Officer, OBRR/DBCD/CRS, U.S. Food & Drug Administration: Clinical Memorandum, EUA 26382, COVID-19 Convalescent Plasma. <https://web.archive.org/web/20210226104738/https://www.fda.gov/media/141480/download>
 183. Fauci A: *On Call—A doctor's journey in public service*. U.S.A.: Penguin Random House, 2024. Pg. 404.
 184. University of Washington: Michaelis-Menten kinetics and Briggs-Haldan kinetics. <https://depts.washington.edu/wmatkins/kinetics/michaelis-menten.html>
 185. Wikipedia: Michaelis-Menten kinetics. https://en.wikipedia.org/wiki/Michaelis-Menten_kinetics
 186. Crespillo C, Moreno S: Antiviral therapy and immunotherapy of COVID-19. *Rev Esp Quimioter* 2021; 34 (Suppl. 1) 57-59. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8683015/pdf/revespquimioter-34-suppl-1-57.pdf>
 187. CDC: Provisional death counts for coronavirus disease 2019 (COVID-19), example Internet Archive capture of Feb 17, 2021. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8683015/pdf/revespquimioter-34-suppl-1-57.pdf>
 188. van de Veerdonk FL, Netea MG, van Deuren M, van der Meer JWM, Brüggermann RJ, van der Hoeven H: Kinins and cytokines in COVID-19: a comprehensive pathophysiological approach. Pre Prints: Posted Not PEER-reviewed. 2020 April 3 <https://www.preprints.org/manuscript/202004.0023/v1>
 189. Duan K, Liu B, Li C, Zhang H, Yu T, Qu J, Zhou M, Chen L, Chen Z, Zhang X, Yang X: Reply to Kesici et al. and Zeng et al.: Blocking the virus and reducing the

inflammatory damage in COVID-19. Proceedings of the National Academy of Sciences. 2020-June 20 <https://www.pnas.org/content/117/23/12529>

First of all, this study was a pilot trial and the aim was to investigate the safety of CP transfusion, which was defined as the primary endpoint (3). We nevertheless also explored the possible therapeutic benefits of CP by examining its effectiveness in neutralizing the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and in ameliorating clinical symptoms and paraclinical criteria in recipients. Indeed, the adverse effect was minor, whereas a quickly improved outcome of 10 severe COVID-19 patients was observed. There are of course a number of issues to be addressed, such as the confirmation of the clinical effectiveness in a phase II controlled, randomized trial.

Second, the objective for CP transfusion in severe COVID-19 therapy is based on an in-depth understanding of disease mechanisms. The pathogenesis of this epidemic involves the interaction between viral replication of SARS-CoV-2 and human immune response (4). Particularly, in severe or critical COVID-19 cases, lung alveolar macrophages or epithelial cells could produce various proinflammatory cytokines and chemokines, which recruit monocytes and neutrophils to the infection site to clear the virus particles and infected cells, resulting in uncontrolled inflammation. The uncontrolled virus infection leads to more macrophage infiltration and a further worsening of lung injury. Therefore, the key point of CP therapy is to neutralize the virus and to interrupt the vicious cycle of excessive activation of the immune response in severe patients. In our study, 200 mL CP containing neutralized antibody above 1:640 rapidly cleared the viremia and achieved clinical improvement. Considering the accessibility of plasma donors, using CP as replacement fluid for the therapeutic plasma exchange may be not feasible.

Third, the optimal treatment time and dose of CP need to be determined by the knowledge on viral proliferative kinetics. Zhou et al. (5) reported that the median viral shedding time was 20.0 d in survival patients. Huang et al. (6) observed that the viral load gradually decreased in the respiratory tract after 7 d of illness onset but can be detected after 28 d of illness onset in two-thirds of critically ill patients. Chen et al. (7) found the serum viremia was detected in 29.4% (5/17) critically ill patients and was significantly correlated with the level of interleukin-6. Thus, monitoring the dynamic changes of interleukin-6 level, which was significantly elevated in COVID-19, may help to determine the optimal treatment time, generally within 2 wk.

Finally, the optimal time for collecting CP should be determined by the time and level of total antibody production in convalescent patients. The presence of antibodies was <40% among patients within 1 wk since onset and rapidly increased to 100.0% (antibody), 94.3% (immunoglobulin M), and 79.8% (immunoglobulin G [IgG]) since day 15 after onset (8). Also, the neutralizing antibody titer was correlated with the IgG antibodies (9). The median duration of hospitalization for COVID-19 patients was 12.0 d (10). In our study, all of the donors were recovered from the common type of COVID-19. Therefore, the collection of CP from the convalescent patients may be 3 wk after the illness onset, and routine inactivation of plasma should be performed for elimination of potential existing virus. The optimal dose of CP can be calculated based on an empirical formula: volume (liters) = weight of the recipient (kilograms) × the antibody titer of CP.

190. Liu STH, Lin HM, Baine I, Wajnberg A, Gumprecht JP, Rahman F, Rodriguez D, Tandon P, Bassily-Marcus A, Bander J, Sanky C, Dupper A, Zheng A, Altman DR, Chen BK, Krammer F, Rao Mendu D, Firpo-Betancourt A, Levin MA, Bagiella E, Casadevall A, Cordon-Cardo C, Jhang JS, Arinsburg SA, Reich DL, Aberg JA, Bouvier NM. Convalescent plasma treatment of severe COVID-19: A matched

control study. medRxiv preprint. Published initially on 2020 September 15 as a medRxiv preprint and subsequently Nature Medicine 2020 November; 26: 1708-1713. <https://www.nature.com/articles/s41591-020-1088-9.pdf>

Abstract Results Convalescent plasma recipients were more likely than control patients to remain the same or have improvements in their supplemental oxygen requirements by post-transfusion day 14, with an odds ratio of 0.86 (95% CI: 0.75~0.98; p=0.028). Plasma recipients also demonstrated improved survival, compared to control patients (log-rank test: p = 0.039). In a covariates-adjusted Cox model, convalescent plasma transfusion improved survival for non-intubated patients (hazard ratio 0.19 (95% CI: 0.05~0.72); p = 0.015), but not for intubated patients (1.24 (0.33~4.67); p=0.752).

Mr. President: What the abstract results above mean is that if the patients require intubation (at the end of the Cytokine Cascade and Bradykinin Storm), then there was no survival advantage to Passive Immunization with COVID-19 Convalescent Plasma.--**BUT**, if COVID-19 Convalescent Plasma was given before intubation, in all analyses in this study, there was a significant survival advantage (i.e.: all p values were < 0.05).

191. Fara A, Miltrev Z, Rosalia RA, Assas BM: Cytokine storm and COVID-19: a chronicle of pro-inflammatory cytokines. The Royal Society publishing – Open Biology. 2020 Sep 23; 10(9): 200160. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7536084/>
192. Parshley L: This theory might explain “Covid toes” and other mysteries of the disease. Vox. 2020 September 19 <https://www.vox.com/21445038/covid-19-symptoms-treatments-bradykinin-cytokine-storm>
193. Fajgenbaum DC: Cytokine storm. N Engl J Med 2020; 383: 2255 – 2273. <https://www.nejm.org/doi/pdf/10.1056/NEJMra2026131?articleTools=true>
194. Karamyan VT: Between two storms, vasoactive peptides or bradykinin underlie severity of COVID-19? The Physiological Society, Physiological Reports REVIEW. 09 March 2021;9 (5):e14796, 1-9. <https://physoc.onlinelibrary.wiley.com/doi/10.14814/phy2.14796>

Abstract

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), continues to be a world-wide pandemic with overwhelming socioeconomic impact. Since inflammation is one of the major causes of COVID-19 complications, the associated molecular mechanisms have been the focus of many studies to better understand this disease and develop improved treatments for patients contracting SARS-CoV-2. Among these, strong emphasis has been placed on pro-inflammatory cytokines, associating severity of COVID-19 with so-called “cytokine storm.” More recently, peptide bradykinin, its dysregulated signaling or “bradykinin storm,” has emerged as a primary mechanism to explain COVID-19-related complications. Unfortunately, this important development may not fully capture the main molecular players that underlie the disease severity. To this end, in this focused review, several

lines of evidence are provided to suggest that in addition to bradykinin, two closely related vasoactive peptides, substance P and neurotensin, are also likely to drive microvascular permeability and inflammation, and be responsible for development of COVID-19 pathology. Furthermore, based on published experimental observations, it is postulated that in addition to ACE and neprilysin, peptidase neurolysin (Nln) is also likely to contribute to accumulation of bradykinin, substance P and neurotensin, and progression of the disease. In conclusion, it is proposed that “vasoactive peptide storm” may underlie severity of COVID-19 and that simultaneous inhibition of all three peptidergic systems could be therapeutically more advantageous rather than modulation of any single mechanism alone.

195. Odeh NH: Roles of a bradykinin storm and a cytokine storm in Covid-19 cases. DigitalCommons--@WayneState-- 2021 August 9
https://digitalcommons.wayne.edu/cgi/viewcontent.cgi?article=1075&context=honors_theses
196. Andrus CH: Thank you letter to Gilead Sciences for providing the reference regarding the date of completion of Phase 1 remdesivir trial. 2022 February 16

From: Charles.Andrus@va.gov,
To: Public_affairs@gilead.com,
Cc: Charles.Andrus@va.gov, candrus600@aol.com, Anthony.Fauci@nih.hhs.gov, kara.harris@nih.hhs.gov, Janet.Woodcock@fda.hhs.gov, Denise.Hinton@hhs.gov, Jacqueline.OShaughnessy@fda.hhs.gov, michael.hogan@va.gov,
Subject: RE: Phase 1 remdesivir trial result
Date: Wed, Feb 16, 2022 3:25 pm
Attachments: 3 Andrus SLU cv 8_11_2021.docx (7964K),

2/16/2022

NIAID Case #12276

Dear Gilead:

Thank you for forwarding this article to me: Humeniuk R, Mathias A, Huyen C, Osinusi A, Shen G, Chng E, Ling J, Wu A, German P: Safety, Tolerability, and Pharmacokinetic of Remdesivir, An antiviral for Treatment of COVID-19, in Healthy Subjects. Clin Transl Sci 2020; 13, 896-906: [Safety, Tolerability, and Pharmacokinetics of Remdesivir, An Antiviral for Treatment of COVID 19, in Healthy Subjects \(wiley.com\)](https://onlinelibrary.wiley.com/doi/10.1002/cltr.2020.13.issue-10). I have attached a copy of my CV so you know who I am. Over my decades of involvement with the Veterans Health Administration (VHA), U.S. Department of Veterans, I have attempted to be an advocate for each and every individual Veteran patient that presented to me. My biggest challenge was to have the phrase in VHA Handbook 1400.1 on Resident Supervision revised (after ~50 years): **Level 3: Attending Surgeon not present, immediately available**. What was condoned by the inappropriate application of Level 3 was that on nights, weekends, holidays, family get togethers, etc., some University Attending Surgeons would staff residents in the OR from afar (ghost surgery). Twenty years ago, I fought for that change all the way to the U.S. Court of Appeals for the Federal Circuit in *Andrus v VA*, Case 03-3162—in which the court *per curiam* “failed to rule.” I lost all my battles with the VA; but, in the end, all Attending Surgeons-of-Record in the VA today are required to be present in the OR suite during every individual Veterans’ operation which is definitely to the betterment of every Veteran patient. The VA saved face by: 1.) changing VAH Handbook from 1400.1 to VAH Handbook 1400.01 so you can’t find previous versions electronically if you don’t know the previous URL.; 2.) as is common practice today, in the agencies of the Executive Branch of the Federal Government, electronically overwrite documents

without designating what has been rescinded or that there was even a previous document; and 3.) I became and still am an *unperson* in the VA from 4/1982-8/2016 since my Official Personnel File (OPF) has been misplaced/lost. Thus, from April 1982 to August 2016, I don't exist in the VA until I returned in August 2016, as an Attending Physician and General Surgeon at the St. Louis VAMC. My VA service from 1982 to 2002 does not exist "officially" even though from 8/1996 to 1/2002, I was the Chief of Surgery, Edward Hines, Jr. VAH (the first hospital of the University-VA affiliation in 1946 under PL-79-293); and I was interviewed for the position of Under Secretary for Health

(USH) of the Veterans Health Administration (VHA), U.S. Department of Veterans Affairs (DVA) on the 10th floor of VACO (across Lafayette Square from *The White House*) on the afternoon of December 10, 1999. I am telling you this, so I can put in context for you the convoluted process regarding Remdesivir that parallels that which occurred to me in my fight to stop Physically Unsupervised resident surgeons by VA misdirection and obfuscation twenty years ago. Today, by changing URLs, electronic overwriting, and semantics, the FDA, the NIH, the CDC, the VA, etc. have somewhat stretched the truth before the American people.

I thank you for forwarding the reference regarding the Phase I studies completed for Remdesivir (RDV). As is quoted in the article:

On May 1, 2020, based on available data from to global clinical trials, the US Food and Drug Administration (FDA) granted emergency use authorization to allow RDV to treat adults and children hospitalized with severe COVID-

19^{19,22,23} Based on these clinical data, RDV has been approved for the treatment of adults and pediatric patients in

Japan.²⁴ This paper describes the safety and pharmacokinetics (PKs) of the solution and lyophilized formulations of i.v. RDV administered to healthy participants in the two first-in-human (FIH) phase I studies.

The above paragraph suggests that the FDA issued the EUA after review of the two first-in-human phase I studies involving Remdesivir (VEKLURY) and that review occurred at least by May 1, 2020, which means that phase I human trials were deemed safe and implies that the phase I trials *de facto* were completed—BUT, that presented multiple ethical and legal dilemmas for the FDA, the NIH, etc.

1. The FDA issued the first Remdesivir EUA on May 1, 2020 (which was the date when Dr. Fauci announced Remdesivir from the Oval Office); yet by making it an EUA, Remdesivir,-- the FDA was defining Remdesivir as an "unapproved" drug in the treatment of COVID-19

2. As phase II/III clinical trials proceeded, prospective participants who had contracted COVID-19 should have been made aware in their Informed Consent that with The Right to Try Act, PL-115-176 that they could still be afforded Remdesivir by non-participation in the mandated RCT placebo trials—for that matter, all of America should have been told of this by the FDA! As the Phase I studies *de facto* were completed, any American could have asked for Remdesivir under PL-115-176 and should have received it!

3. As I am sure that you are well-aware that Remdesivir is "a single diastereomeric monophoramidate prodrug that inhibits viral RNA polymerases" which works best during the initial

viremic phase of COVID-19—rather than in the later severe disease phases of cytokine cascade and bradykinin storm. Unfortunately, with the issuance of the EUA on May 1, 2020, “the US Food and Drug Administration (FDA) granted emergency use authorization to allow RDV to treat adults and children hospitalized with severe COVID-19^{19,22,23}.” In fact, the FDA removed the severity stipulation quietly--not notifying the American public of this significant retraction--on August 28, 2020. In the FDA January 21, 2022 letter to Madelyn Low, MBS, Manager, Regulatory Affairs, Gilead Sciences, Inc., <https://www.gilead.com/-/media/files/pdfs/remdesivir/eua-fda-authorization-letter.pdf?la=en&hash=FD3737583BE0E4DF710ADB36AEA2DBD>, there are 8 references on pages 1 and 2 in which the Acting Chief Scientist of FDA outlined the chronology regarding Remdesivir including the August 28, 2020 retraction of the severity of illness stipulation: “...FDA revised authorized use of Veklury to no longer limit its use for the treatment of patients with severe disease.” (How could Remdesivir being an “unapproved” drug in the treatment of COVID-19 under the FDA’s EUAs standards become a drug that the FDA was officially revising authorization so it could be given early in the course of the disease? It seems like a bunch of semantics; but if that bunch of semantics limits the rights of individuals in America, that is wrong.

4. “On October 22, 2020, FDA also approved NDA 214787 for Veklury for the treatment of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 Kg) requiring hospitalization.” At this point, Remdesivir (VEKLURY) was designated by the FDA as a prescription drug (NDA 214787) on October 22, 2020.

5. In November 2020, the Veterans Health Administration (VHA) of the U.S. Department of Veterans Affairs issued for the fully-FDA- authorized-prescription drug, VEKLURY, NDA 214787 the: “Remdesivir (VEKLURY) Criteria for Use” of how to administer Remdesivir with the severity Inclusion Criteria exclusively included that had been removed previously on August 28, 2020 by the FDA:

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) Criteria for Use November 2020
VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives
<small>The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS PAT COMMITTEE AND PHARMACY SERVICES.</small>
<small>The Product Information should be consulted for detailed prescribing information.</small>
<small>See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or http://www.pbm.va.gov for further information.</small>
Exclusion Criteria
<small>If the answer to ANY item below is met, then the patient should NOT receive remdesivir</small>
<input type="checkbox"/> Treated for COVID-19 as an outpatient
<input type="checkbox"/> AST or ALT > 5 times the upper limit of normal
<input type="checkbox"/> Hospitalized patients but NOT requiring supplemental oxygen*
<input type="checkbox"/> Concomitant use of hydroxychloroquine or chloroquine
<input type="checkbox"/> Current eGFR < 30 mL/min**
Inclusion Criteria
<small>The following must be fulfilled in order to meet criteria for remdesivir</small>
<input type="checkbox"/> Hospitalized with SEVERE COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)***
Supplemental Information
<small>Recommended initial duration of therapy is 5 days, with the potential to extend to 10 days in patients who are not improving or who remain critically ill. Therapy can be discontinued when the patient is appropriate for discharge, even if the full duration of therapy has not been given</small>
<small>*Use in hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe disease may be appropriate and should be adjudicated on a case by case basis</small>
<small>**Patients with eGFR < 30 mL/min (or CrCl < 30-50 mL/min depending on the trial) were excluded from clinical trials and routine use is not recommended by the manufacturer. Use may be considered and adjudicated on a case by case basis if the benefit is felt to outweigh the risks, especially when renal function is likely to improve rapidly (e.g. dehydration). The mechanism of calculating renal function can be based on local guidance.</small>
<small>***Remdesivir alone is not recommended alone for patients on mechanical ventilation or ECMO but may be considered in conjunction with corticosteroids in patients who have recently been intubated, according to the NIH Treatment Guidelines for COVID-19</small>

Prepared: November 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

Updated version may be found at [PBM INTERNET](#) or [PBM INTRAnet](#)

6. When I had a patient denied Remdesivir by the Infectious Diseases service quoting the November VA directive, I contacted Richard Stone, M.D., VHA Chief Medical Executive (the Trump Administration's title for the Under Secretary for Health, VHA, DVA). Dr. Stone contacted VA Pharmacy Management Services and the Medical Advisory Board. At first, the VA responded to me. But when the VA became evasive, I contacted the FDA, the NIAID (Case #12276), and wrote a letter to the editors of the *The New England Journal of Medicine*. None responded to me.

7. I recently had a patient admitted to the Surgical Service who had newly turned COVID-19 positive (less than 24 hours from negative to positive). The recommendations from the same Infectious Diseases service was that if the patient had any symptomatology like headache or neck pain, give three days of Remdesivir; and if the patient develops a cough, give five days of Remdesivir and dexamethasone. By the time of that consult, the CDC had stated a month before that Regeneron's and Eli Lilly's monoclonal cocktails were ineffective against COVID-19, omicron variant; and, thus, GlaxoSmithKline's *sotrovimab* was and is being *de facto* rationed at present time.

Once again, I thank all involved in addressing my question at Gilead regarding if a phase I study had been completed in the case of Remdesivir. You were all very professional and willing to listen—and, most of all, my personal thanks as a Federal Physician and Surgeon for you have provided this information which may become an outstanding service for the people of the United States of America.

Thank you,
Charles Andrus, M.D., F.A.C.S.
Professor, Department of Surgery, Saint Louis University School of Medicine

Chief and Attending General Surgeon, Unit II (SLU) General Surgery division, Surgical Service,
John Cochran (112JC), St. Louis, MO 63106

Office phone: 314-652-4100 ext 54463 Beeper: 314-491-2417
Home phone: 314-455-9482

P.S. I hope this e-mail will initiate an overall discussion regarding transparency by the agencies of the U.S. Government in regards to the EARLY (< 72 hours from diagnosis) administration with intent of synergism of COVID-19 Convalescent Plasma, COVID-19 monoclonal antibodies, Remdesivir and other future antivirals, etc. Respectfully, Charles H. Andrus, M.D., F.A.C.S.

From: Public Affairs <Public_affairs@gilead.com>
Sent: Wednesday, February 16, 2022 7:54 AM
To: Andrus, Charles H. (STL) <Charles.Andrus@va.gov>
Subject: [EXTERNAL] Phase 1 remdesivir trial results

Dr. Andrus, You can find the published results of the Phase 1 remdesivir trial here:
<https://ascpt.onlinelibrary.wiley.com/doi/10.1111/cts.12840>

Thank you for your inquiry,

Gilead Public Affairs

Discussion

197. Karaosmanoglu HK: Did the COVID-19 pandemic make scientists forget “Primum Non-Nocere”, one of the most important principles of bioethics? *Acta Biomed* 2021; 92(2): e2021221. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8182591/pdf/ACTA-92-221.pdf>
198. Pavia CS, Wormser: Passive immunization and its rebirth in the era of the COVID-19 pandemic. *International Journal of Antimicrobial Agents* 2021 March; 57(3): 106275. <https://pmc.ncbi.nlm.nih.gov/articles/PMC7834679/pdf/main.pdf>
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On September 9, 1887, Dr. Harvey Cushing, then a resident in Surgery at The Johns Hopkins Hospital, operated on a patient with a ruptured appendix. The patient died ten days later of peritonitis. This experience must have increased his apprehension when, on Sunday, September 26, 1887, Cushing experienced abdominal pain and carefully recorded the development of his own episode of acute appendicitis (Fig. 14). At 9:00 am the following morning, he was seen in consultation by Drs. Halsted and Osler who did not advise operation. At 2:00 pm on the same day, he was taken to the operating room where Dr. Halstead removed his appendix. A somewhat complicated recovery followed (fig. 15).
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America's Fight Against Coronavirus, SARS-CoV-2, COVID-19 with mRNA vaccine prophylaxis (monoclonal *Active Immunization*) alone *without implementation* FOR ALL infected with COVID-19 with synergistic, early treatment (<96 hours from diagnosis) with exogenous immunoglobulins (*Passive Immunization*) and antivirals

OR

Euphemistical Obfuscation in Clinical Medicine, *Jesuitical* Lies by Omission and Paltering, Subliminal Bait-and-Switch, and Machiavellianism Resulting in 1,000,000+ Deaths and America's Defeat by the Non-sentient Coronavirus, SARS-CoV-2, COVID-19

Charles H. Andrus, M.D., F.A.C.S.

Former Professor (Tenured), Department of Surgery, Saint Louis University SOM

Former Professor and Vice-Chairman, Department of Surgery, Loyola University SOM and

Chief, Surgical Services, Edward Hines, Jr. VAH

Former Federal Whistleblower at the direction of the VA OIG and VHA Medical Inspector –

U.S. Office of Special Counsel, files MA-00-1107, DI-00-1147

U.S. Court of Appeals for the Federal Circuit, Case# 03-3162 (EEOC case 210A36145X)

NIAID Case #12276, U.S. National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID)

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November 1, 2024

In a publicity website for the new memoir of Anthony Fauci, M.D., former Director of the National Institute of Allergy and Infectious Diseases (NIAID): *On Call – A Doctor's Journey in Public Service*¹, it opens with: “The memoir by the doctor who became a beacon of hope for millions through the COVID pandemic, and whose six-decade career in high-level public service put him in the room with seven presidents.”² In his book at least 19 times, Dr. Fauci alluded to the compatibility of having had a Jesuit education and his devotion to public service.¹ In fact, during the first spring of COVID-19 U.S. epidemic, Dr. Fauci explicitly stated this in an interview with Dr. Howard Bauchner, M.D., then editor-in-chief of the *Journal of the American Medical Association* (JAMA)³:

Dr Bauchner: Your equanimity, does it come from your parents? Does it come from your Jesuit education? It's extraordinary under the face of remarkable criticism, almost always unfair.

Dr Fauci: I think it does come a lot from my parents. My father was very much of a tolerant person who would accept people for what they are and very rarely ever criticized anybody. I went to a Jesuit high school in Manhattan, and from there I went to a Jesuit college. I think it was just right for me because I had always been interested in public service and not being somebody that ever attacks anybody, that accepts them for who they are and what they are. So it was kind of the perfect atmosphere to me to be educated in, and I just carried it along with me.

I agree with Dr. Fauci that my years with Jesuit^{4,5} education and my public service as a physician and surgeon of the Veterans Health Administration (VHA), U.S. Department of Veterans Affairs (DVA) (Attachment I) Includes references 6-11, Andrus *Curriculum vitae* is reference 12 .

St. Ignatius College Preparatory, SF, 1967-1971;
University of San Francisco, BS in Chemistry, *summa cum laude*, 1971-1975;
Saint Louis University SOM, Doctor of Medicine, 1975-1979;
Residencies in Pediatrics, 1979-1981 and General Surgery, 1981-1986
at the Affiliated Hospitals of St. Louis University SOM (SLUSOM);
faculty, SLUSOM 1986-1996 and my public service as a Physician and Surgeon,
Veterans Health Administration, U.S. Department of Veterans Affairs (1982-1996)
faculty, Loyola University SOM, Chicago 1996-2001 and my public service
as a Physician, Surgeon, and the Chief of Surgical Services, Edward Hines Jr. VAH, Veterans
Health Administration, U.S. Department of Veterans Affairs (1996-2002)
faculty, SLUSOM (2006-2020) and my public service as a Physician and Surgeon,
Veterans Health Administration, U.S. Department of Veterans Affairs (1982-1996, 2016-2022)

were compatible and paramount in my outlook as a physician and surgeon with all the altruistic mottos I have practiced under in Medicine and Surgery during my professional life¹²:

“Primum non Nocere” – First, do no harm Hippocrates¹³⁻¹⁵

Ad Majorem Dei Gloriam – To the Greater Glory of God St. Ignatius of Loyola¹⁶⁻¹⁸

...to care for him who shall have borne the battle, and his widow, and his orphan... Abraham Lincoln¹⁹

...Moreover, I promise to deal with each patient as I would wish to be dealt with were I in his position...

Fellowship American College of Surgeons Pledge²⁰

...the secret in the care of the patient is in caring for the patient. Dr. Francis W. Peabody^{21,22}.

“Men for Others” Father Pedro Arupe, S.J.^{1,23-25}

By the very design of the University-VA affiliation of 1946, PL-79-293^{26,27} and VA Policy Memorandum #2²⁸ and my personal involvement in the clinical and educational entities listed above, as an American Board of Surgery Certified General Surgeon, I¹² was employed professionally for 25 years^{11- pages e262-e264} during my four decades as both an Academic and Federal Physician and Surgeon in the University-VA systems^{29,30} which were established to be harmonious-in-intent and purposeful-in-focus regarding: First, and foremost, the care of our fellow man—and, in the case of the VA, the Veteran patient⁷⁻¹⁴ as outlined in Attachment 1 as President Abraham Lincoln promised for all of us for all times:

...to care for him who shall have borne the battle, and for his widow, and his orphan...¹⁹

On December 10, 1999, I was one of five physicians interviewed in the 10th floor “Secretary’s Conference Room of VA Central Office (across Lafayette Square from *The White House*) by the VHA USH Commission for the position of the VA Under Secretary for Health (USH) 38 U.S. Code § 7301^{31,32}, U.S. Department of Veterans Affairs (Andrus⁷⁻¹³, Bowen^{10,33}, Garthwaite^{10,34,35}, Petzel^{10,36-41}, Roswell^{10,42-43}). As Dr. Bowen’s name and mine were not advanced to *The White House* for subsequent vetting and ultimate submission and approval by the Senate to the position of VHA USH, my daily role for over 25 years of officially-documented public service^{11- pages e262-e264} in the VA was principally that of a General Surgeon, Clinician, funded Researcher for a 4-year period of time, and as an advocate for my patients within the U.S. Department of Veterans Affairs.¹² While Dr. Fauci may have been “in the room of seven presidents”², I was probably considered more of an annoyance (burr-in-the-saddle) to only the five most-recent presidencies in my advocacy for appropriate patient care for all throughout my 32 years as an Attending Physician and General Surgeon in the Jesuit^{4,5} medical school educational system and ~25 years within the U.S. Department of Veterans Affairs.

Ironically, other participants throughout history who attended or taught within Jesuit^{4,5} education in the past besides Dr. Fauci¹ and myself¹² are: Sir Arthur Ignatius Conan Doyle⁴⁴, René Descartes⁴⁵, Pope Francis⁴⁶, Fidel Castro⁴⁷, former President Bill Clinton (1993-2001)⁴⁸, Associate Supreme Court Justice Clarence Thomas⁴⁹⁻⁵⁰, Associate Supreme Court Justice Neil Gorsuch⁵¹⁻⁵³, Associate Supreme Court Justice Brett Kavanaugh⁵¹⁻⁵³, and former President Donald J. Trump (2017-2021)⁵⁴⁻⁵⁶—to name just a few. While Justice Thomas⁴⁹ and I¹² were inducted into the Jesuit^{4,5} Honor Society--AΣN⁵⁷—during our undergraduate collegiate years, recently Dr. Fauci became an honorary AΣN member through Georgetown University in the acknowledgement of his pivotal role in our nation’s fight during the COVID-19 epidemic.^{58,59} In the religious formation, instruction, and development of a Jesuit^{4,5} scholastic and/or newly ordained priests and brothers (trainees of the Society of Jesus^{4,5} of the Catholic Church—*The Jesuits*^{4,5}), one of the courses of study is that of Apologetics⁶⁰—the art of the debate in the defense of the Faith. While the term *Jesuitical*^{61,62} primarily means being a member of the Society of Jesus^{4,5}, the second alternate meaning has a pejorative connotation of being *slickly equivocal*. Hopefully, not exploiting the second definition of *Jesuitical*^{61,62}, I will employ in this paper the apologetical technique of *reductio ad absurdum*^{1,11,12,63-65} --Attachment II—reduce the argument to the absurd--to point out how we, all too often, as a society and especially today in the Practice of Medicine, have fallen into the trap of believing that which individually suits us for self-promotion and advancement (much too often to the detriment of others).

Such a mindset is a prevalent, all-too-common, subliminal form of the application of Machiavellianism⁶⁶⁻⁶⁸ in our present-day American society: *The end justifies the means*.⁶⁹⁻⁷⁰ At all levels of American life today (e.g.: personal interactions, business, academia, politics, and, most especially Medicine), *the end justifies the means*⁶⁹⁻⁷⁰, has become all-too-pervasive, subliminally surreptitious, and blatantly a bait-and-switch⁷¹ fostered by **lies of commission, lies of omission, and paltering**.⁷²⁻⁷⁶

Such is in contrast to *Veritas Vincit Omnia*⁷⁷⁻⁷⁸ -- *Truth Conquers All*. While a half-of-a-millennium overdue, in December 1999, St. Pope John Paul II apologized to the Bohemian people (today the Czech Republic) for the execution of Jan Hus who is credited in publicizing the phrase *Veritas Vincit Omnia* in 1413. Today, does Jan Hus' admonition: *Veritas Vincit Omnia* even have any relevance in American society?

Prior to this article's in-depth analysis of U.S. Medicine's emphasis during the COVID-19 pandemic on vaccination/**PROPHYLAXIS** for COVID-19 (Active Immunization) and failure to utilize in an organized fashion early **TREATMENT** (within 72-96 hours after diagnosis) with immunoglobulins (Passive Immunization) and antivirals, what immediately follows are a few examples of foundational and historical disregard of *the facts*, obfuscation of the truth, and **lies of commission or omission and/or paltering**—some are innocuous while others have had the potential to lead us to a societal retrogressional mindset:

Example 1, **Paltering** (*The Methodology of the Riddle*): While on a car-rally-date on a Saturday night during my college years, I was posed with the inconsequential riddle at one of the rally-route checkpoints which went something like this:

If a rooster is perched on the peak of a barn roof with the pitched sides of the roof facing west to east, the western portion of roof being angled at ~10 degrees while the eastern portion is at ~5 degrees, and the wind is blowing from west to east at 15 knots, when the chicken lays the egg, which side of the barn roof will it roll down?—After a moment of consideration, the correct answer was that roosters don't lay eggs.

While the rooster perched on the barn roof, the dimensions of the barn, the direction and speed of the wind, and that chickens lay eggs are individually truthful, this is a harmless, somewhat humorous example of **Paltering**⁷⁵ in which:

Paltering is active use of truthful statements to convey a misleading impression. ...

All too often today in our analysis in applying foundational / fundamental information, we become distracted by the extraneous rhetoric and subliminal lies of commission or omission and fall victims to our yearnings to rush to a judgment for a definitive conclusion disregarding foundational teachings and doctrine.

Example 2, **Errors of Omission**: Throughout the Biden administration, one of the major focused environmental projects has been the removal of all y66 pipes from all potable water

systems throughout the United States.⁷⁹⁻⁸⁸ While water systems contaminated from lead pipes, lead solder, galvanized pipes contaminated with lead *ortho*-phosphate, etc. are probably the major ongoing cause of lead exposure throughout the United States, the EPA still proports to all rehabilitation-contractors that⁸⁹:

WHERE DOES THE LEAD COME FROM?

Dust is the main problem.

The most common way to get lead in the body is from dust. Lead dust comes from deteriorating lead-based paint and lead-contaminated soil that gets tracked into your home. This dust may accumulate to unsafe levels. Then, normal hand to-mouth activities, like playing and eating (especially in young children), move that dust from surfaces like floors and window sills into the body.

Since the 1990s, though, most water systems throughout the United States have employed *ortho*-phosphate additives precipitating lead salts in lead pipes and also in downstream galvanized iron (and cast iron) pipes thus decreasing the solubilized concentrations of the oxides and hydroxides of lead ions.⁹⁰⁻⁹¹ When Flint, Michigan switched from Detroit water to its own sources, addition of *ortho*-phosphates were mistakenly overlooked and subsequently the tap water downstream from lead pipes and in the older homes of Flint which had cast iron pipes downstream from the lead pipes feeding their homes and/or galvanized pipes within the homes turned red, smelled, and tested positive for high levels of lead (Pb).⁹³⁻⁹⁶ As long as there is galvanized/iron piping in individual housing, businesses, playground water-fountains, etc. that were previously downstream from lead pipes whose water supplies were treated with *ortho*-phosphates, increased levels of lead will continue to be detectable in the populous of our country due to the slow solubilization of precipitated lead salts over time from contaminated corroded pipes previously downstream from the lead pipes as was noted in a JAMA Pediatrics article of March 18, 2024: “Estimated Childhood Lead Exposure from Drinking Water in Chicago.” While removal of all the lead pipes in this country has been estimated to take at least a decade into the future to accomplish, (1) what of the downstream iron pipes that are contaminated by precipitated lead phosphates^{90,91,93-96} and (2) what about the other associated ongoing human morbidity?⁹⁸ Should chelation therapy be advocated for those testing positive for elevated serum lead levels as our water supplies are being extirpated of lead contamination?^{99,100}

While removing all the lead pipes in drinking from throughout the United States is a medically and ethically mandated project¹⁰¹⁻¹⁰² long overdue, the omission of the consideration of the downstream internally-rust-corroded iron pipes contaminated with lead *ortho*-phosphate precipitates throughout the nation over the last 2-3 decades is an ongoing environmental and epidemiological silently ubiquitous catastrophe. The most recent review article entitled Lead Poisoning in the *New England Journal of Medicine* of October 31, 2024 provides an extensive history but fails to mention downstream galvanized/iron plumbing nor orthophosphosphates.¹⁰³ Whether calculated or unintended, the disregard / **omission** of the knowledge of the solubility of lead in drinking water—no matter how small—is affected by phosphate additives in the water and most consistent with what occurred in Flint, Michigan¹⁰⁴:

Hydroxypyromorphite (HPM) is a low-solubility Pb phosphate mineral that has the potential to limit solubility and bioavailability of Pb in soils and water. Because of reported uncertainty regarding the solubility product of this important mineral, we re-evaluated the solubility of Pb and activity of the free

Pb²⁺ ion in aqueous suspensions of microcrystalline HPM equilibrated up to 30 days over a wide range of added soluble phosphate. A small addition of phosphate (0.1 mM) reduced Pb solubility as measured by ICP-OES, but greater phosphate additions (up to 50 mM) had no further effect in lowering HPM solubility. However, free Pb²⁺ ion activity measured by ion-selective electrode progressively decreased from about 10^{-6.5} with no added phosphate to 10⁻⁹ as soluble phosphate was increased. The effect of soluble phosphate in lowering Pb²⁺ activity is attributed to inhibited dissolution of HPM as well as increased Pb²⁺-phosphate ion pair formation in solution at higher solution concentrations of phosphate. Measurement of the ion activity products (IAP) of the solutions at equilibrium with HPM gave highly variable IAP values that were sensitive to pH and were generally not consistent with the reported solubility product of this mineral. The high variability of the IAPs for solutions with variable pH and phosphate concentrations indicates that dissolution precipitation reactions of HPM are not described by a constant solubility product at equilibrium, possibly because of the incongruent dissolution behavior of this mineral at near-neutral pH.

By the simple **Omission** of disregarding *the finite solubility of an inorganic compound in solution*, United States society has condemned *ad infinitum* anyone drinking water from contaminated galvanized / iron pipes that are or were downstream of lead pipes treated with *orthophosphates* for any period of time to the potential of continued chronic lead exposure.

Example 3, Lies of Commission and Omission, Paltering, and Political Meanness and

Immorality: In the Winter of 2023-2024, anticipated Republican-presidential-nominee Trump persuaded the Republicans of Congress to disavow a bipartisan bill of the Senate for immigration reform so he could make immigration reform the keystone issue of his campaign for President of the United States in 2024.¹⁰⁵⁻¹⁰⁹ Migrants on the USA/Mexican border were demonized in the media by the former President¹¹⁰⁻¹¹⁴; migrants were transported across state lines to northern cities¹¹⁵⁻¹¹⁹ at the approval of legislatures and governors of some of southern states in what, I would allege, were violations of the Lindbergh law of 1932, PL-72-189, 18 U.S.C. 1201¹²⁰; and potentially-passive lethal impediments were deployed in defiance of a U.S. Supreme Court ruling.¹²¹⁻¹²⁴ Does the Governor of a State with no border contiguous with the country of Mexico¹²⁵ have the authority to send the National Guard when according Article I, Section 8, Clause 11 of the U.S. Constitution only Congress has the authority to declare war?¹²⁶⁻¹²⁸ On the other side of the argument, could the President of the United States federalize those same National Guard troops to perform humanitarian efforts with regards to all those not-of-this-country that are crossing the border?¹²⁹⁻¹³² Ironically, the National Guard sent to the U.S.-Mexico border could be federalized by the President to do good for these desperate people rather than create impediments to their very existence.

It is estimated by the U.S. Border Patrol that from FY 1998 to 2022, about 9,520 migrant deaths¹³³⁻¹³⁶ were reported within U.S. borders of the continental United States of America in their attempts to cross the Mexican/USA border. So much for:

- 1) We hold these truths self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness.—That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed,—That whenever any Form of Government becomes destructive of these ends, it is the Right of the People to alter or to abolish it, and to institute new Government, laying its foundation on

such principles and organizing its powers in such form, as to them shall seem most likely to effect their Safety and Happiness. from the Declaration of Independence¹³⁷

- 2) ...“Give me your tired, your poor,
Your huddled masses yearning to breathe free,
The wretched refuse of your teeming shore.
Send these, the homeless, tempest-tost to me,
I lift my lamp beside the golden door!” from Emma Lazarus’s sonnet about the Statue of Liberty¹³⁸

To modify the stalemate, President Biden worked throughout 2023 to facilitate a bipartisan effort to address the problem^{139,140} but finally unilaterally announced on June 4, 2024, new actions to secure the border.¹⁴¹ In short, though:

The underlying moral barbarism still remains--Disregard for Individual Human worth of which we should all be ashamed!¹⁴²⁻¹⁴⁵

Example 4. Paltering in the Analytical Evaluation and Analysis, Resultant Public Health Policy Misdirection, and Untreated Deaths for over a quarter of a century:

Since 1998, the monoclonal antibody palivizumab (Synagis)^{146,147} was approved as a prescription drug in the prophylaxis of Respiratory Syncytial Virus (RSV)¹⁴⁸⁻¹⁵⁰ by the FDA in high risk neonates/infants only. Prior to the COVID-19 American epidemic in 2018, Dr. Fauci as the senior author of¹⁵¹:

Marston HD, Paules C, Fauci AS: Monoclonal antibodies for emerging infectious diseases – Borrowing from history. N Engl J Med 2018 Apr 19; 378 (16): 1469 – 1472.
https://www.nejm.org/doi/10.1056/NEJMp1802256?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed ,
<https://www.nejm.org/doi/10.1056/NEJMo002465/full/>

was interviewed by Dr. Morrissey of *The New England Journal of Medicine* and stated¹⁵²:
<https://www.nejm.org/action/showMediaPlayer?doi=10.1056%2FNEJMo002465&aid=10.1056%2FNEJMp1802256&area=:>

Well, for example, a classic monoclonal antibody for prophylaxis against Respiratory Syncytial Virus has been developed with considerable success. ...

While the monoclonal antibody palivizumab against RSV is one of present-day immunological science’s greatest success stories per the interview of Dr. Fauci and one of the best examples of Passive Immunization¹⁵³⁻¹⁵⁹, (and now nirsevimab¹⁶⁰⁻¹⁶⁵ (Beyfortus)), it has been *de facto* rationed in clinical medicine since 1998 directed solely by the FDA as **prophylaxis only in high-risk infants**.¹⁵⁹⁻¹⁷² The adult medical literature has completely ignored palivizumab as an early (<96 hours from diagnosis) passive immunologic treatment of RSV for all. Since 1998, the CDC has reported an annual mortality of 300 in children and in adults over age 65 from 6000-10,000 individuals per year which calculates to 150,000 to 250,000 untreated deaths in adults over age 65 years over the last quarter century.¹⁷³⁻¹⁷⁵ While treatment in infants¹⁷⁶⁻¹⁷⁸ has been studied with no difference in length of hospitalization used as the only endpoint¹⁷⁹⁻¹⁸⁷, there have

been no studies regarding treatment (not prophylaxis) at any age group with the endpoint being death (which is 200-330 times greater annually in adults than children). This **paltering application and FDA-directed practice of medicine regulating** palivizumab by de facto rationing with FDA approval of prophylaxis only in infants only¹⁶⁴⁻¹⁷¹—and not treatment to prevent death--is akin to the unethical withholding of penicillin for treatment in the Tuskegee Syphilis Project^{188,189} of the mid-twentieth century--but at a national level. For the last quarter of a century, a magnified total death toll in adult RSV disease has been documented by the CDC to be 250-400 times when compared that observed resultant in the participants in Tuskegee Syphilis Project (due fortuitously to the limited patient population (~600 patient subjects—399 with syphilis and 201 controls without syphilis) in the Tuskegee Syphilis Project.

As an editor since 1983, Dr. Fauci's name^{1(pp.237-238)} is recognizable "from the frequently updated medical textbook *Harrison's Principles of Internal Medicine*"¹⁹⁰ to the large number of physicians who were exposed to this major textbook: "... while they were in medical school and during their residency training." To the present, Dr. Fauci has been an editor of eleven editions (11th-21st editions) of which he was the overall editor-in-chief of two: the 14th and 17th editions.^{190, p ii} Without ever explaining the logic and principles of immunology or clinical medical practice since 1998 of restricting palivizumab to prophylaxis in high risk infants only, palivizumab is mentioned five times in the greater than 3855 pages of the 21st edition of *Harrison's Principles of Internal Medicine*¹⁹⁰:

1. Both RSV and parainfluenza viruses, particularly type 3, can cause severe or even fatal pneumonia in HSC transplant recipients. Infections with both these agents sometimes occur as disastrous nosocomial epidemics. Therapy with **palivizumab** or ribavirin for RSV infection remains controversial. (page 1140)
2. **Palivizumab** **Palivizumab**, a humanized monoclonal antibody to RSV F protein, is approved for prevention of lower respiratory tract disease due to RSV in pediatric patients at high risk of RSV disease, including premature infants and children with bronchopulmonary dysplasia. (page 1464)
3. **PASSIVE PROTECTION WITH IMMUNOTHERAPY**
Palivizumab, a humanized mouse monoclonal antibody to the F protein of RSV, is licensed for prevention of RSV hospitalization in high-risk infants, in half or more of whom it is effective. (page 1513)
4. **Palivizumab**, 1140, 1464, 1513. (page I-164)

The foundational essence of the FDA's regulatory functions began in 1906 with the enactment of the Pure Food and Drugs Act, PL-59-384.¹⁹¹⁻¹⁹³ The history¹⁹⁴⁻²⁰⁵ of its mandate to regulate and protect the American public (never to dictate medical practice) has progressed, evolved, and matured over the years.^{206,207} Unfortunately, although the RSV story over the last twenty-five years is mired in confusion regarding treatment versus prophylaxis and selection bias between pediatric and adult internal medicine research, application in clinical Medicine today is best typified by the ancient parable of India of the Blind Men and the Elephant.²⁰⁸ What has resulted today is a hodgepodge of processes and policies that exclude or ignore appropriate application of passive immunization and antivirals *as treatment* during the viremic phase of a viral infection (<72-96 hours). In essence, the FDA regulations have been used to develop restrictive policies *de facto* proscribing immunoglobulin treatment uses in infected individuals with the resultant consequence of the FDA de facto prescribing daily Clinical Medical Practice devoid of early immunotherapy at all ages which was never the intent nor within the scope of the legal mandate of the U.S. Food and Drug Administration.

A prospective study using palivizumab as a *Passive Immunization treatment* was performed in RSV infected infants¹⁷⁷ and no difference was demonstratable in which the only chosen primary endpoint of hospital length-of-stay which has too many associated variations fails to study that which should be the primary endpoint of death. As the incidence of annual mortality from RSV in infants (~300 per year) and in adults is 6,000 – 10,000 per year^{173-175, 209}, death as the primary endpoint in a randomized controlled trial (RCT) would not be finitely feasible and would be considered unethical. Even still, no comparable RTC utilizing length-of-stay as the primary endpoint in adults has been reported. Even though the adult mortality is estimated to be 20 times higher than that of infants, a prospective RCT with palivizumab and/or nirsevimab as *Passive Immunization* treatments early (not prophylaxis) in the course of the disease (<72-96 hours) still would not be feasible with death as the endpoint as the annual mortality incidence is small in adults and any RCT would not be finitely feasible and would be considered unethical. With a previous 25-year national experience, though, an age-matched controlled trial (AMCT) with palivizumab or nirsevimab as *Passive Immunization treatments* versus historic control non-immunologic treatments would be feasible and ethical.

Until recently (2023 going forward), the statement: “There are currently no targeted prophylactic, therapeutic, or vaccine options for RSV in older adults, and treatment is limited to offering supportive care for adults with the illness”²⁰⁹ was true due in a large part to the paucity in research in therapeutically addressing RSV in adults²⁰⁹:

RSV bronchiolitis is the leading cause of infant hospitalization due to viral respiratory illness, characterized by respiratory distress that can result in death. There is no specific treatment for RSV, only supportive care measures like oxygen and fluids. Currently, there is no vaccine to help prevent RSV in the U.S., leaving most infants without protection. The only available preventive agent is recommended for use among the highest-risk infants in limited settings as a monthly injection with five doses administered during the RSV season.

Among adults 65 years and older, RSV infections account for approximately 60,000–160,000 hospitalizations and 6,000–10,000 deaths each year in the U.S. alone.^{11,12,13,14,15,16,17,18} There are currently no targeted prophylactic, therapeutic, or vaccine options for RSV in older adults, and treatment is limited to offering supportive care for adults with the illness.

With the development of the RSV vaccines²⁰⁹⁻²¹⁴ (Active Immunization), prophylactic protocols are now being aggressively promoted and marketed²¹⁵⁻²¹⁸ for adults 65-74 years of age and >75 years and pregnant mothers between 32 and 38 weeks gestation²¹⁹⁻²²³ without any overall/universal immunological principle/protocol explanations regarding treatment of infected individuals. While the vaccine in the mother stimulates endogenous immunoglobulins production by *Active Immunization* in the mother, the fetus receives these immunoglobulins via the placenta of the mother as exogenous immunoglobulins by *Passive Immunization* with the finite life-span in the child of 2 - 6 months ($t_{1/2}$ = 36-38 days).^{159,162} Administered exogenous RSV monoclonal antibodies reportedly have half-lives of: $t_{1/2}$ = 21-88 days for palivizumab¹⁵⁹ and $t_{1/2}$ of 68.7 ± 10.9 days for nirsevimab²²⁴ (and, for nirsevimab, a half-life range of 80 – 120 days^{167,225}).

Like with other members of the *Paramyxoviridae* virus family (mumps, measles viruses, etc.)^{226,227}, a more prudent long-term, epidemiologically-sound mandated process would be to

vaccinate every child (the vectors for the family and society) at ~6 months to 1 year of age with a subsequent booster at ~6 years to promote the long-term minimization of the annual seasonal epidemics of bronchiolitis, etc. When any individual regardless of age requires hospitalization due to RSV infection, then *Passive Immunization* (e.g.: palivizumab^{146-172,177,190}, nirsevimab^{160-165,167,224,225}, etc.) and antiviral treatments (e.g.: ribavirin (virazole) and other chemotherapeutic agents in the future)²²⁸⁻²³⁰, should be administered regardless of previous vaccination status as these treatment maneuvers, especially synergistically, may be life-saving.

The **Paltering** story of the prophylaxis and lack-of-treatment of Respiratory Syncytial Virus (RSV) infections in children and adults is riddled with ignorance, incomplete analyses, and aggressive marketing by the pharmaceutical companies producing vaccines and continuing restrictions of the monoclonal antibody **Palivizumab** by the FDA of a quarter of a century to only high risk infants with the exclusion of non-high-risk infants, children, and adults. (One of the overriding subliminal prohibitive restrictions in the treatment (not prophylaxis) of RSV with palivizumab can be summed up in the statement: ***“However, palivizumab is only available for high-risk children in developed countries due to prohibitive costs.”***²³⁰)

Ironically, in the **phase I study of the extended half-life MEDI8897** (NCT02114268)^{231, 232}, “a fully human anti-RSV prefusion F monoclonal antibody with increased potency and an extended half-life” was carried out not in children or infants but in healthy adults ages 18 to 49 years with the following results²³¹:

Except for 1 subject who had a 4-fold increase in neutralizing antibody titer, possibly due to an RSV infection or exposure, subjects in the placebo group had stable titers for the duration of the study (mean titer range, 8.2 to 8.6 log₂). Among those receiving MEDI8897, RSV neutralizing antibody titers increased in a dose-dependent manner (Fig. 3). The highest titers were detected 8h postinfusion in those receiving an i.v. dose and on day 6 in those receiving an i.m. dose. At 8 h postinfusion, the geometric mean fold rise in titers was 0.96, 27.4, 33.8, and 96.0 among subjects receiving placebo or MEDI8897 at 300 mg i.v., 1,000 mg i.v., and 3,000 mg i.v., respectively. This geometric mean fold rise in titers on day 6 was 1.1, 13.6, and 12.5 for placebo, MEDI8897 at 10 mg i.m., and MEDI8897 at 300 mg i.m., respectively. On day 31, neutralizing antibody titers had increased ≥4-fold relative to baseline levels in 100% of subjects receiving an i.v. dose of MEDI8897 and 83% and 91% of subjects receiving 100 mg i.m. and 300 mg i.m. MEDI8897, respectively. This ≥4-fold increase in neutralizing antibody titers from baseline persisted until day 181 in 60%, 80%, 83%, 50%, and 55% of subjects receiving 300 mg i.v., 1,000 mg i.v., 3,000 mg i.v., 100 i.m., and 300 mg i.m. MEDI8897, respectively. Neutralizing antibody titers were lower in the 300-mg i.m. group than in the 300-mg i.v. group at 8 h following administration but were comparable at day 6 through the end of the study. In general, administration of MEDI8897 resulted in increased levels of neutralizing antibodies that were maintained above background levels for up to 1 year.

MEDI8897 is the “Other product name(s)” for the FDA approved established/proper name *Nirsevimab* and the “(Proposed) proprietary name” of *Beyfortus*.²³³ “In July 2023, the Food and Drug Administration approved nirsevimab^{160-164,167-170,172,178,231-237}, “a long-acting monoclonal antibody, for passive immunization to prevent RSV-associated lower respiratory tract infection among infant and young children.”

Regardless of financial constraints resulting in immunoglobulin and antiviral rationing and selective capital opportunities for pharmaceutical company profits^{228,230}, hopefully, in the future an organized, **truthful**, clinical algorithm will be established in the *Passive Immunization* treatment, as well as, prophylaxis—not just infants—**BUT for all ages**. Who will organize such

a process (e.g.: NIH, FDA, PHS, CDC, Academic Medicine, *Harrison's Principles of Internal Medicine*¹⁹⁰, etc.)? And, if an organized set of protocol(s) are developed, how will such protocols utilizing appropriate, comprehensive, all-inclusive *Active* and *Passive Immunization* and antiviral therapies enter into the general medical literature so as to encourage daily clinical applications to encompass and be appropriately implemented for all stages of life **in the treatment (and prophylaxis)** of RSV infection in: the fetus, the neonate, all family members regardless of age, and the >60 year-old population?

CONCLUSION:

America's Fight Against Coronavirus, SARS-CoV-2, COVID-19

with mRNA vaccine prophylaxis (monoclonal *Active Immunization*) alone *without implementation* FOR ALL infected with COVID-19 with

synergistic, early treatment (<96 hours from diagnosis) with exogenous immunoglobulins (*Passive Immunization*) and antivirals

OR

Euphemistical Obfuscation in Clinical Medicine, *Jesuitical* Lies by Omission and Paltering, Subliminal Bait-and-Switch, and Machiavellianism Resulting in 1,000,000+ Deaths and America's Defeat by the Non-sentient Coronavirus, SARS-CoV-2, COVID-19

was an explanation of the previous definition of the terminology of ***PALTERING*** with some unrelated but pertinent examples of the pervasive methodology of ***PALTERING***. In our American society today, ***paltering*** permeates our daily societal interactions pervasively throughout all walks of life especially in medical explanations to the American public. Specifically, this in-depth dissertation on ***Paltering*** is **Attachment I** to the paper:

Generalized Dismissal of Early Treatment with Passive Immunization and Antivirals (Not Prophylaxis/ Active Immunization) in Persons Infected with COVID-19

regarding the American COVID-19 Epidemic in which U.S. Medicine and the American public were inundated with a potpourri of disorganized facts, theories, and political maturations. In our response to COVID-19, U.S. Medicine organizationally:

- (1) failed to outline for the American public the pathophysiology of a SARS-CoV-2 infection,
- (2) failed to make the distinction between **Treatment** of an infected individual (with i.e.: Immunotherapy—*Passive Immunization* and Antivirals) and **Prophylaxis** (with i.e.: vaccines-*Active Immunization*), and, in so doing,
- (3) U.S. Medicine facilitated / tolerated a **disregard and dismissal for the early treatment** (not prophylaxis) within 72-96 hours of diagnosis of individuals infected with coronavirus, SARS-CoV-2, (COVID-19) with the appropriate application of exogenous immunoglobulins and antivirals in an organized, non-rationing, financially-equitable fashion, etc.

The rest of these **Attachments (II – VII)** provide other documentation that address, analyze, and discuss other facets regarding the failure to develop an appropriate, organized early treatment (<72 – 96 hours from diagnosis) of every individual infected with coronavirus, SARS-CoV-2, regardless of individual's vaccination status. On April 1st, 2020, (seemingly *apropos* as April 1st is April Fools Day) Nora O'Donnell on the nightly CBS News posed the following inquisitorial statement after which Dr. Fauci responded with a self-apparent truism which has epitomized the last five years of America's confrontation with the COVID-19 global pandemic²³⁸:

Norah O'Donnell: With all due respect it does seem like so much of this we're making it up as we go along.

Dr. Anthony Fauci: Well, you know you make it up as you go along, Norah, because that's what you know—that's where the war is all about. I don't like to necessarily make that analogy to a war, but if you talk to the generals with experience, you have a plan. But when the bullets start flying, everything becomes a fog, and you have to play it by ear. We do have a good plan. We need to be humble that we don't know all the answers, and we don't know how exactly this is going to turn out.

Norah O'Donnell: Dr. Fauci, thank you so very much for your time and expertise.

Dr. Anthony Fauci: It's always good to be with you, Norah. Thank you.

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https://www.va.gov/oaa/1400_1hk_Oct2001.doc returns the VA official website which states: **Sorry – we can’t find that page.** Using the Wayback Machine, for 2004-10-28: http://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400_1hk_Oct2001.doc which states on pages 8 – 9:

(3) **Level 3.** The staff practitioner is immediately available in the facility – campus for direct resident supervision according to local policy as approved by the Network Academic Affiliations Officer. The service chief is responsible for periodically reviewing cases done under Level 3 supervision to ensure that such supervision is appropriate.

Using the Wayback Machine another version of the Level 3 Supervision (now Level D) is identified: In VHA Handbook of July 27, 2005 signed by Jonathan B. Perlin, M.D. https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400_1hk_July_27_05.doc (Recission of the previous version of May 3, 2004 which cannot be found):

4. **Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.

Using the only other “hit” on the Wayback Machine of December 21, 2016, http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400_1hk_Oct2001.doc VHA 1400.1 has been removed completely and in its place is the website of the U.S. Department of Veterans Affairs which states: “Page Not Found.” **De facto, the U.S. DVA, VHA**

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4. Level D: Attending in OR Suite, Immediately Available. The supervising practitioner is physically present in the operative or procedural suite and able to provide direct supervision or consultation without delay as needed. (page 9)

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Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts. https://web.archive.org/web/20140814150238/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

40. Petzel RA: Utilization of Physician Assistants (PA), VHA Directive 1063 (1), Veterans Health Administration, U.S. Department of Veterans Affairs, December 24, 2013. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 which is redirected when accessed to AMENDED June 24, 2024. Captured on July 22, 2023, by the *Internet Archive*. https://web.archive.org/web/20230722070741/https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2958 In **2. SUMMARY OF CHANGES** of the **Transmittal Sheet** which is still labelled **December 24, 2013** but in red has stamped: **AMENDED May 17, 2022** is: (1) Paragraphs 2.c. and 2.e. removes references to the Supremacy Clause reference and physician liability.—which means that the independent practice of a VHA Physician Assistant was rescinded returning all Physicians Assistants to the State Medical Board statutes outlining mandatory Physician scope of practice affiliations and legally mandated Physician oversight. The signatory official on this document is Robert A. Petzel, M.D., Under Secretary for Health who had been terminated over the Phoenix VAMC scandal 8 years prior to this as noted above in references 36 and 37.

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After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired Fighting for Care narrated by Diane Sawyer. 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Temple, TX VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, ABC News PrimeTime Live, for "Fighting for Care," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents— I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Temple TX VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

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Antibodies have been used for a century for the prevention and treatment of infectious diseases (Table 1). In bacterial disease, antibodies neutralize toxins, facilitate opsonization, and, with complement, promote bacteriolysis; in viral disease, antibodies block viral entry into uninfected cells, promote antibody-directed cell-mediated cytotoxicity by natural killer cells, and neutralize virus alone or with the participation of complement.

Prior to the use of antibiotics, antibodies were the only specific agents for the treatment of certain infections. Although this role has largely been supplanted by antibiotics, there still remains a crucial role for antibody in the treatment of certain infectious diseases (Table 1). Since several excellent reviews are available, this article will emphasize new developments (30, 31, 101, 164, 165).

Antibodies can be administered as human or animal plasma or serum, as pooled human immunoglobulin for intravenous (IVIG) or intramuscular (IG) use, as high-titer human IVIG or IG from immunized or convalescing donors, and as monoclonal antibodies (Mab) (30, 164, 178). The therapeutic use of Mab is increasing dramatically, but only one (palivizumab for respiratory syncytial virus [RSV]) has been licensed for prophylaxis of an infectious disease.

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Footnote at bottom of every page of this Annotated Bibliographic Timeline:

----- May 30, 2022 -----
 This is a COVID-19 Timeline Bibliography for Educational Purposes ONLY in the presentation of this information before the people of the United States³ of America (U.S.A.), the World, and specifically the President of the U.S.A. without any compensation to the author. All submissions including this timeline bibliography can be obtained under the Freedom of Information Act (FOIA) by formally requesting a copy of NIAID Case #12276 from the FIOA Officer of the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health, Bethesda, Maryland

Treatment: *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

Prevention: *Active Immunization:* Vaccines

This submission is NOT for financial gain but for educational purposes only for ALL the American people

Attachment II: List of Accompanying Documents to Dr. Andrus' response letter of March 4, 2024, to President Joseph Biden in Dr. Andrus' response to President Biden's letter of July 7, 2023

Dear Reader, Please note that March 4, 2024, was the 159th year anniversary day of President Abraham Lincoln's second inaugural address in which he promised from all of us for all times:

...to care for him who shall have borne the battle, and for his widow and his orphan...

Book 1: Andrus CH: *Book 1: Dear Mr. President: COVID-19 and Where We Went Wrong 2023 02 02*. Internet Archive, uploaded: 2023-09-12, pages: 1 - 1266. NIH NIAID Case #12276.

<https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02/>

[*Description:* This is a copy of Book 1: Dear Mr. President...COVID-19 and Where We Went Wrong first submitted to agencies of the DHHS, the DVA, and the President of the United States in September 2022. It has been edited over the last year but is still in draft form. What is more, the submission to the Internet Archive is for NO personal financial gain. As a former VHA physician and surgeon of the U.S. Department of Veterans Affairs, it is (1) my duty as a former federal physician and (2) mandate to the oath I swore professing *Primum non Nocere*, that today, I submit this to the American people as a purely educational contribution that should be debated, analyzed, and appropriately acted upon by U.S. Medicine, the FDA, the NIH, the NIAID, the VA, etc. Respectfully, Charles H. Andrus, M.D., F.A.C.S.]

Book 2: Andrus CH: *0 2023 09 11 Scan VA RSSO Case 286816 Letter Arrived Feb 13 2023*. Internet Archive, uploaded: 2023-09-11. NIH NIAID Case #12276. Pages 1-3 plus 5 additional attached .pdf files:

<https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/0%202023-09-11%20scan%20VA%20RSSO%20Case%20286816%20letter%20arrived%20Feb%2013%202023/>

Pages 1-3:

[*Description:* This is the final cover letter from the VA Workforce Management & Consulting (WMC), Retirement Shared Service Office (RSSO), VA RSSO Case #286816 received by Dr. Andrus on Feb 13, 2023, with the 18 lbs of documentation submitted by Dr. Andrus on January 30, 2023 per the request of the VA RSSO. The fourth paragraph inappropriately closed the door on the recalculated back pay of ~\$82,000 owed to Dr. Andrus and revision of his monthly pension by: "...after speaking with leadership, it was determined to return the documents you have mailed in as they are not pertinent to your salary discrepancy or the retirement."]

The five additional .pdf files attached to this Internet Archive upload.

01 2023-01-29 cover Andrus e-mail transmission to VA.pdf <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/01%202023-01-29%20cover%20Andrus%20e-mail%20transmission%20to%20VA%20/>

03 Appendix C VA Commendations Andrus 2023-01-28.pdf <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/3%20Appendix%20C%20VA%20Commendations%20Andrus%202023-01-28/page/n3/mode/1up>

04 Appendix D Andrus 2023-01-29.pdf. <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/4%20Appendix%20D%20Andrus%202023-01-29/>

05 SF-50s including 01-19-2002 45.remarks Constructive Discharge.pdf. <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/5%20SF-50s%20including%2001-19-2002%2045.remarks%20Constructive%20Discharge/>

06 1999-11-12 VA OIG report Hines VAH CAP 99-00173-18 <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/6%201999-11-12%20VA%20OIG%20report%20Hines%20VAH%20CAP%2099-00173-18/> This file is only a space filler as the VA OIG Website URL has been removed by the VA of: <https://www.va.gov/oig/pubs/99-00173-18> Therefore, I uploaded to the Internet Archive a copy of the VA

Office of Inspector General's: *Combined Assessment Program Review, Edward Hines, Jr. VA Hospital, Hines, IL*, Report No. 99-00173-18, Date: November 22, 1999 to:

06.3005 1999 11 22 Hines VAH CAP 99 00173 18 Copy Charles H. Andrus, M.D., F.A.C.S. uploaded as this VA OIG report was published for PUBLIC RELEASE by the U.S. Department of Veterans Affairs, Office of Inspector General on November 22, 1999. Internet Archive, upload March 2, 2024.

<https://archive.org/details/06.3005-1999-11-22-hines-vah-cap-99-00173-18-copy>

Topics: U.S. Department of Veterans Affairs, Office of Inspector General, CAP Review, Edward Hines, Jr. VA Hospital, Report No. 99-00173-18, November 22, 1999, <https://www.va.gov/oig/pubs/99-00173-18.pdf>

[Description:

The VA OIG website for the Hines VAH CAP 99-00173-18 has been removed from the VA OIG Website URL: <https://www.va.gov/oig/pubs/99-00173-18.pdf> which today yields: "Sorry, we can't find that page"; and this VA OIG Website URL was never uploaded to the Internet Archive over the last 25 years. Thus, on 3/2/2024, I uploaded in a .pdf format a scanned copy of the complete VA OIG report No. 99-00173-18 of November 22, 1999, signed off by Richard J. Griffin, DVA Inspector General, which was 48 pages in length: title page, i-v, 1-42. This scanned copy is contained in its entirety in Chapter 6 of the—as yet, not uploaded-- unabridged Book 3, pages 192-259: 06.3005 1999-11-22_Hines_VAH_CAP_99-00173-18.pdf.

In October/November 1999, roughly 4 weeks prior to the publication of this report by the VA OIG, a young man from the regional IG office on the Hines VAH grounds presented to my Hines VAH office on the fifth floor of Building 200 and asked if I had any documentation of OR resident supervision at the Hines VAH. I, immediately, provided him with a 3 ½" diskette which contained the latest monthly report on resident supervision by surgical specialty never realizing that the VA OIG would publish it. It consisted of: A monthly cover letter on Attending Surgeon supervisory levels of residents and an Excel data base entitled Surgery Resident Supervision in OR—FY 99 (the last 17 pages of APPENDIX IV, pages 43-61 of 99-00173-18). (An abridged version of this report can be found on pages 277-283 of Book 3: <https://archive.org/details/book-3-abridged-dear-mr-president...-to-care-for-him-who-shall-have-borne-the-battle-2024-02-29/> . While the title page states VA OIG report No. 99-00173-18 was **FULLY-REDACTED**, the VA OIG did not redact my name from the cover letter as I was one of the two named signatories on page 44 of the report. (This VA OIG official report confirms I existed as the Chief of Surgery, Edward Hines, Jr. VA Hospital, Hines, IL on October 14, 1999, which contradicts the official search of the U.S. National Archives for the existence of my Official Personnel File (OPF) from 1982 to 2002 as is documented on page 533 of Book 3 <https://archive.org/details/book-3-abridged-dear-mr-president...-to-care-for-him-who-shall-have-borne-the-battle-2024-02-29/> .)

In the letter on page 1 of Book 2: Andrus CH: 0 2023 09 11 Scan VA RSSO Case 286816 Letter Arrived Feb 13 2023. Internet Archive, uploaded: 2023-09-11.

[https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/0%202023-09-](https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/0%202023-09-11%20scan%20VA%20RSSO%20Case%20286816%20letter%20arrived%20Feb%2013%202023/)

[11%20scan%20VA%20RSSO%20Case%20286816%20letter%20arrived%20Feb%2013%202023/](https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/11%20scan%20VA%20RSSO%20Case%20286816%20letter%20arrived%20Feb%2013%202023/) it is stated by the RSSO official: "...In addition, after speaking with leadership, it was determined to return the documents you have mailed in as they are not pertinent to your salary discrepancy or the retirement."

When I resigned from the VHA in January 2002, my Grade and Step was 15-10. When I returned to the VHA in August 2016, I was designated by the VHA as a Physician and Surgeon as a 15-07, a *de facto* demotion, as there reportedly was no confirmation of my 18 years of service in the VHA from 1982-2002. As is documented on page 4 of 3

Appendix C VA Commendations Andrus 2023-01-29 [https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/3%20Appendix%20C%20VA%20Commendations%20Andrus%202023-01-](https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/3%20Appendix%20C%20VA%20Commendations%20Andrus%202023-01-29/)

[28/page/n3/mode/1up](#) , I retired with 25 years of service which under Title 38, U.S.C. Sec. 7431, qualified me to be the rank of Grade 15 Step 13 (instead of Grade 15 Step 10). *Res ipsa loquitur*: I should have a retirement rank of Grade/Step of 15-13, my calculated outstanding back pay is ~\$82,000, and my retirement pension should be recalculated by the RSSO of the DVA for the last 6 years of my VHA service from 2016 – 2022 as my Step and Grade should have been from 15-10 to a 15-13 (Not 15-7 to 15 – 10).

Respectfully,

Charles Andrus, M.D., F.A.C.S.]

Book 3: Andrus CH: *Abridged Dear Mr. President: "...to care for him who shall have borne the battle..."* A. Lincoln Internet Archive, uploaded: 2024-02-29, pages 1-534. NIH NIAID case #12276 <https://archive.org/details/book-3-abridged-dear-mr-president...-to-care-for-him-who-shall-have-borne-the-battle-2024-02-29>

Topics: IL-372, PATH, Physicians at Teaching Hospitals, Veterans Health Administration, Resident Supervision, to care for him who shall have borne the battle

[Description: This is an abridged version of the yet to be uploaded Dear Mr. President...To Care for Him Who Shall Have Borne the Battle...A. Lincoln Which is a composite (of > 3500 pages) of this abridged version of Book 3--A confirmatory chronological compendium of primary sources and resultant correspondence between Dr. Andrus and:

- (1) the U.S. Department of Veterans Affairs [VA OIG 2000 HL-0347, 9HL-015, U.S. DVA ORM/EEO 200k-1886; U.S. EEOC 03A20075, 210-A2-6164X, 210-A3-6145X, etc.],
 - (2) the U.S. Merit Systems Protection Board,
 - (3) the EEOC,
 - (4) the U.S. Court of Appeals for the Federal Circuit, docket case #03-3162,
 - (5) the Veterans Affairs Committee of the U.S. House of Representatives,
 - (6) the U.S. Office of Special Counsel [MA-00-1107, DI-00-1147],
 - (7) the U.S. Department of Justice, (8) The White House,
 - (9) Academic and Research Medical Organizations and Medical Societies (e.g.: the CDC, AMA, ACS, NIH NIAID case #12276 between 2020 - the present, etc.) and the staffs of the NEJM, JAMA, American Journal of Surgery, etc.,
- and other academic and research entities of American Medicine.

The central issue of this book covering over 5 decades is allegations of **the *de facto* denial of care, the *de facto* dereliction to duty, and the *de facto* disregard of patients' rights by some Teaching Physicians and Surgeons in the condoning of Ghost Surgery for a half-century.** (Ghost Surgery: Attending Surgeon supervising but not physically being present during the performance of operations, procedures, and encounters by physicians-in-training [residents].) This book documents the misapplications by some of the Rules of Attending Surgeon Supervision as mandated in the private and public section under **Intermediary Letter 372 (IL-372)** of the Social Security Administration and in the Veterans Health Administration under **VHA Handbook 1400.1**.

Much of the subsequent correspondence is permeated with legal obfuscation and chronic denial.

Submitted respectfully as is my duty as a retired Physician and Surgeon, Veterans Health Administration, U.S. Department of Veterans Affairs,

Charles H. Andrus, M.D., F.A.C.S.

--former Chief, Surgical Services, Edward Hines, Jr. VAH, Maywood, IL (tertiary Chicago VA hospital and first VAH of the University/VA affiliation in 1946, PL 79-293), Veterans Health Administration (VHA), U.S. Department of Veterans Affairs (1996 - 2002)

--former Professor and Vice-chairman, Department of Surgery, Loyola University School of Medicine (1996- 2001)

--retired Attending Surgeon (and for most of the time, Chief, Unit II General Surgery--Saint Louis University GS division), John Cochran (St. Louis) VAMC, Veterans Health Administration, U.S. Department of Veterans Affairs (1986 - 1996) and (2016 - 2022)

--retired Professor and Surgeon, Department of Surgery, Saint Louis University School of Medicine (2006 - 2022); Medical Student: 1975 - 1979, Pediatric Resident: 1979 - 1981, General Surgery Resident: 1981 - 1986, faculty: 1986 - 1996, 2006 - 2022.

Book 4: Andrus CH: *Book 4: Biden Response to The Summary of Book 1 COVID 19 And Where We Went Wrong*. Internet Archive, Uploaded 2024 Feb 05, [Only 382 pages loaded] <https://archive.org/details/book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong/> , *** Uploaded again on March 5, 2024 to the Internet Archive and all 848 pages were uploaded. Title: 0.4 Book 4 Biden response to the Summary of Book 1 COVID 19 And Where We Went Wrong 2nd Attempt , *Internet Archive* , uploaded March 5, 2024. pages 1- 848 <https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attempt> *** NIH NIAID Case #12276

[Description: On July 7, 2023, President Joseph Biden replied to the included summary submission of Book 1: Dear Mr. President: COVID-19 and Where We Went Wrong. <https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02/>

NIH NIAID Case#12276. Book 1 is 1266 pages documenting correspondence with the NIAID, the FDA, the VA, and The White House over 3 years concerning the clinical care of patients newly infected with COVID-19. All the documentation that has been submitted to the NIH NIAID Case #12276

(Book 1 is an abridged documentation) is available through the Freedom of Information Act Officer of the NIAID. The submissions to the NIAID and FDA in detail outlined the pathophysiology of coronavirus SARS-CoV-2; the difference between Active Immunization (vaccination for PROPHYLAXIS to stimulate endogenous immunoglobulins) vs Passive Immunization in the TREATMENT of acute COVID-19 [within 72 - 120 hours of diagnosis] through the administration of exogenous immunoglobulins, e.g.: Convalescent Plasma, Monoclonal Antibodies, and Monoclonal Antibody cocktails, etc.); describe extreme misinformation and obfuscation by the NIH, NIAID, FDA, etc.; describe in-depth the inappropriate late timing of administration of immunoglobulins and antivirals (>120 hours from diagnosis of acute infection); and the cover-up by governmental, academic, etc. entities by electronic overwriting, URL site relabeling/renaming, and website removal; officials, medical researchers, academics, and clinicians, and agencies advancing incorrect or misleading medical statistics and theories that were associated with and were possibly contributory to >1,000,000 reported deaths from COVID-19 in the U.S.A. from March 2020 to the present. -- Charles H. Andrus, M.D., F.A.C.S.]

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(3) **Level 3.** The staff practitioner is immediately available in the facility – campus for direct resident supervision according to local policy as approved by the Network Academic Affiliations Officer. The service chief is responsible for periodically reviewing cases done under Level 3 supervision to ensure that such supervision is appropriate.

Using the Wayback Machine another version of the Level 3 Supervision (now Level D) is identified: In VHA Handbook of July 27, 2005 signed by Jonathan B. Perlin, M.D. https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400_1hk_July_27_05.doc (Recission of the previous version of May 3, 2004 which cannot be found):

4. **Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.

Using the only other “hit” on the Wayback Machine of December 21, 2016, http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400_1hk_Oct2001.doc VHA 1400.1 has been removed completely and in its place is the website of the U.S. Department of Veterans Affairs which states: “Page Not Found.” **De facto, the U.S. DVA, VHA**

misdirected official government documentation which is tantamount to destruction of evidence used in the trial of Andrus v VA, U.S. Court of Appeals for the Federal Circuit, docket # 03-3162.

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37. Chaggaris S: Top VA official's resignation "is a termination." CBS NEWS, 2014 May 16 <https://www.cbsnews.com/news/white-house-top-va-officials-resignation-is-a-termination/>

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5. RECISSIONS. VHA Handbook 1400.1, Resident Supervision, dated July 27, 2005 is rescinded..... (page 1). *[Please note that when one searches for VHA Handbook 1400.1, Resident Supervision, dated July 27, 2005, one is redirected to VHA Handbook 1400.01. Using the Wayback Machine and the previous URL for VHA 1400:* http://web.archive.org/web/20161221045318/https://www.va.gov/oa/1400_1hk_Oct2001.doc , one can find the 2001 version in the 2004 of the Internet Archive captures. There are no other captures of this URL in the Wayback Machine except December 21, 2016 which brings up the VA Website which states: "Page Not Found."

4. Level D: Attending in OR Suite, Immediately Available. The supervising practitioner is physically present in the operative or procedural suite and able to provide direct supervision or consultation without delay as needed. (page 9)

39. Petzel RA: Utilization of Physician Assistants (PA), VHA Directive 1063, Veterans Health Administration, U.S. Department of Veterans Affairs, December 24, 2013. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 which is redirected when accessed to AMENDED June 24, 2024. The original version of VHA Directive 1063 of December 24, 2013 which claimed physician assistants could be independent practitioners -- which I would allege is a violation of every State Medical Boards' credentialing policies/laws regarding Physician Assistants. In the 2013 version, the justification of the violation of all State Medical Boards was in 2.c:

Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts.

https://web.archive.org/web/20140814150238/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

40. Petzel RA: Utilization of Physician Assistants (PA), VHA Directive 1063 (1), Veterans Health Administration, U.S. Department of Veterans Affairs, December 24, 2013. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 which is redirected when accessed to AMENDED June 24, 2024. Captured on July 22, 2023, by the *Internet Archive*. https://web.archive.org/web/20230722070741/https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2958 In **2. SUMMARY OF CHANGES** of the **Transmittal Sheet** which is still labelled **December 24, 2013** but in red has stamped: **AMENDED May 17, 2022** is: (1) Paragraphs 2.c. and 2.e. removes references to the Supremacy Clause reference and physician liability.—which means that the independent practice of a VHA Physician Assistant was rescinded returning all Physicians Assistants to the State Medical Board statutes outlining mandatory Physician scope of practice affiliations and legally mandated Physician oversight. The signatory official on this document is Robert A. Petzel, M.D., Under Secretary for Health who had been terminated over the Phoenix VAMC scandal 8 years prior to this as noted above in references 36 and 37.
41. Petzel RA: Utilization of Physician Assistants (PA) VHA Directive 1063(2), December 24, 2013 **AMENDED June 24, 2024**. When one uses a search engine like GOOGLE or enters the official URL of this document site: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 , one is electronically shifted to a .pdf file, e.g.: [file:///Users/andrusmd1/Downloads/1063\(2\)_D_2013-12-24%20\(6\).pdf](file:///Users/andrusmd1/Downloads/1063(2)_D_2013-12-24%20(6).pdf). The <https://...> URL version was captured by the *Internet Archive* on July 18, 2024. The signatory official on this document is still Robert A. Petzel, M.D., Under Secretary for Health, who had been terminated over the Phoenix VAMC scandal 10 years prior to this as noted above in references 36 and 37. https://web.archive.org/web/20240718212213/https://www.va.gov/VHApublishations/ViewPublication.asp?pub_ID=2958
42. VA | News: VA Under Secretary for Health resigns. 2004 Apr 5. <https://news.va.gov/press-room/va-under-secretary-for-health-resigns/>
43. Sawyer D: Fighting For Care, ABC News Primetime Live, 8 April 2004 <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>).

After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired Fighting for Care narrated by Diane Sawyer. 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Temple, TX VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, ABC News PrimeTime Live, for "Fighting for Care," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents— I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Temple TX VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

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Antibodies have been used for a century for the prevention and treatment of infectious diseases (Table 1). In bacterial disease, antibodies neutralize toxins, facilitate opsonization, and, with complement, promote bacteriolysis; in viral disease, antibodies block viral entry into uninfected cells, promote antibody-directed cell-mediated cytotoxicity by natural killer cells, and neutralize virus alone or with the participation of complement.

Prior to the use of antibiotics, antibodies were the only specific agents for the treatment of certain infections. Although this role has largely been supplanted by antibiotics, there still remains a crucial role for antibody in the treatment of certain infectious diseases (Table 1). Since several excellent reviews are available, this article will emphasize new developments (30, 31, 101, 164, 165).

Antibodies can be administered as human or animal plasma or serum, as pooled human immunoglobulin for intravenous (IVIG) or intramuscular (IG) use, as high-titer human IVIG or IG from immunized or convalescing donors, and as monoclonal antibodies (Mab) (30, 164, 178). The therapeutic use of Mab is increasing dramatically, but only one (palivizumab for respiratory syncytial virus [RSV]) has been licensed for prophylaxis of an infectious disease.

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Footnote at bottom of every page of this Annotated Bibliographic Timeline:

----- May 30, 2022 -----
 This is a COVID-19 Timeline Bibliography for Educational Purposes ONLY in the presentation of this information before the people of the United States³ of America (U.S.A.), the World, and specifically the President of the U.S.A. without any compensation to the author. All submissions including this timeline bibliography can be obtained under the Freedom of Information Act (FOIA) by formally requesting a copy of NIAID Case #12276 from the FIOA Officer of the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health, Bethesda, Maryland

Treatment: *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

Prevention: *Active Immunization:* Vaccines

This submission is NOT for financial gain but for educational purposes only for ALL the American people

ATTACHMENT VI: Face page for *Reductio ad Absurdum*: The COVID-19 Tale of Two Presidents. The draft of this incomplete article can be found in reference 11: Andrus CH: *Book 4: Biden Response to The Summary of Book 1 COVID 19 And Where We Went Wrong*. Internet Archive, Uploaded 2024 Feb 05, pages e31-e130 of e848.
<https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attempt> *** NIH NIAID Case #12276

***Reductio ad Absurdum*:¹**

The COVID-19 Tale of Two Presidents, the Ramifications of Fifty Years of American Scandal, Therapeutic Nihilism, and Medical Stupidity:

Euphemisms²³⁹: Experimental / Investigational / EUA,
Expanded Access / Compassionate Care
FDA Authorization vs FDA Approval,
Treatment vs Prophylaxis,
Active Immunization vs Passive Immunization, etc.,

FDA Archiving reliance on non-governmental sites

FDA [archived web material](#)  is maintained within the Pagefreezer platform.¹

and loss of information by *electronic overwriting* and *destruction* of URLs,

FDA and NIH blatant, total disregard of the Right to Try Act (PL-115-176) by
never declaring a completed Phase 1 (Safety) [vs Phase 2/3 Efficacy]
Clinical Trial and thus dismissing and *de facto* legally violating PL-115-176

Statistical Misdirection,

Predatory Marketing, and

**> 1.1 million Americans dead associated with withholding early (within 72-120
hours of diagnosis) synergistic treatment with **Exogenous Immunoglobulins**
(Passive Immunization) and Antivirals**

Contingent on: Ignorance, Sins of Ommission, Conflicts-of-Interest, Greed

***“Reform must come from within, not from without.
You cannot legislate for Virtue”*** James Cardinal Gibbons, “Prince of Democracy”

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(3) **Level 3.** The staff practitioner is immediately available in the facility – campus for direct resident supervision according to local policy as approved by the Network Academic Affiliations Officer. The service chief is responsible for periodically reviewing cases done under Level 3 supervision to ensure that such supervision is appropriate.

Using the Wayback Machine another version of the Level 3 Supervision (now Level D) is identified: In VHA Handbook of July 27, 2005 signed by Jonathan B. Perlin, M.D. https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400_1hk_July_27_05.doc (Recission of the previous version of May 3, 2004 which cannot be found):

4. **Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.

Using the only other “hit” on the Wayback Machine of December 21, 2016, http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400_1hk_Oct2001.doc VHA 1400.1 has been removed completely and in its place is the website of the U.S. Department of Veterans Affairs which states: “Page Not Found.” **De facto, the U.S. DVA, VHA**

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5. RECISSIONS. VHA Handbook 1400.1, Resident Supervision, dated July 27, 2005 is rescinded..... (page 1). *[Please note that when one searches for VHA Handbook 1400.1, Resident Supervision, dated July 27, 2005, one is redirected to VHA Handbook 1400.01. Using the Wayback Machine and the previous URL for VHA 1400: http://web.archive.org/web/20161221045318/https://www.va.gov/oa/1400_1hk_Oct2001.doc, one can find the 2001 version in the 2004 of the Internet Archive captures. There are no other captures of this URL in the Wayback Machine except December 21, 2016 which brings up the VA Website which states: "Page Not Found."*

4. Level D: Attending in OR Suite, Immediately Available. The supervising practitioner is physically present in the operative or procedural suite and able to provide direct supervision or consultation without delay as needed. (page 9)

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Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts. https://web.archive.org/web/20140814150238/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

40. Petzel RA: Utilization of Physician Assistants (PA), VHA Directive 1063 (1), Veterans Health Administration, U.S. Department of Veterans Affairs, December 24, 2013. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 which is redirected when accessed to AMENDED June 24, 2024. Captured on July 22, 2023, by the *Internet Archive*. https://web.archive.org/web/20230722070741/https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2958 In **2. SUMMARY OF CHANGES** of the **Transmittal Sheet** which is still labelled **December 24, 2013** but in red has stamped: **AMENDED May 17, 2022** is: (1) Paragraphs 2.c. and 2.e. removes references to the Supremacy Clause reference and physician liability.—which means that the independent practice of a VHA Physician Assistant was rescinded returning all Physicians Assistants to the State Medical Board statutes outlining mandatory Physician scope of practice affiliations and legally mandated Physician oversight. The signatory official on this document is Robert A. Petzel, M.D., Under Secretary for Health who had been terminated over the Phoenix VAMC scandal 8 years prior to this as noted above in references 36 and 37.

41. Petzel RA: Utilization of Physician Assistants (PA) VHA Directive 1063(2), December 24, 2013 **AMENDED June 24, 2024**. When one uses a search engine like GOOGLE or enters the official URL of this document site: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 , one is electronically shifted to a .pdf file, e.g.: [file:///Users/andrusmd1/Downloads/1063\(2\)_D_2013-12-24%20\(6\).pdf](file:///Users/andrusmd1/Downloads/1063(2)_D_2013-12-24%20(6).pdf). The <https://...> URL version was captured by the *Internet Archive* on July 18, 2024. The signatory official on this document is still Robert A. Petzel, M.D., Under Secretary for Health, who had been terminated over the Phoenix VAMC scandal 10 years prior to this as noted above in references 36 and 37. https://web.archive.org/web/20240718212213/https://www.va.gov/VHApublishations/ViewPublication.asp?pub_ID=2958

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After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired Fighting for Care narrated by Diane Sawyer. 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Temple, TX VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, ABC News PrimeTime Live, for "Fighting for Care," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents— I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Temple TX VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

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Antibodies have been used for a century for the prevention and treatment of infectious diseases (Table 1). In bacterial disease, antibodies neutralize toxins, facilitate opsonization, and, with complement, promote bacteriolysis; in viral disease, antibodies block viral entry into uninfected cells, promote antibody-directed cell-mediated cytotoxicity by natural killer cells, and neutralize virus alone or with the participation of complement.

Prior to the use of antibiotics, antibodies were the only specific agents for the treatment of certain infections. Although this role has largely been supplanted by antibiotics, there still remains a crucial role for antibody in the treatment of certain infectious diseases (Table 1). Since several excellent reviews are available, this article will emphasize new developments (30, 31, 101, 164, 165).

Antibodies can be administered as human or animal plasma or serum, as pooled human immunoglobulin for intravenous (IVIG) or intramuscular (IG) use, as high-titer human IVIG or IG from immunized or convalescing donors, and as monoclonal antibodies (Mab) (30, 164, 178). The therapeutic use of Mab is increasing dramatically, but only one (palivizumab for respiratory syncytial virus [RSV]) has been licensed for prophylaxis of an infectious disease.

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Footnote at bottom of every page of this Annotated Bibliographic Timeline:

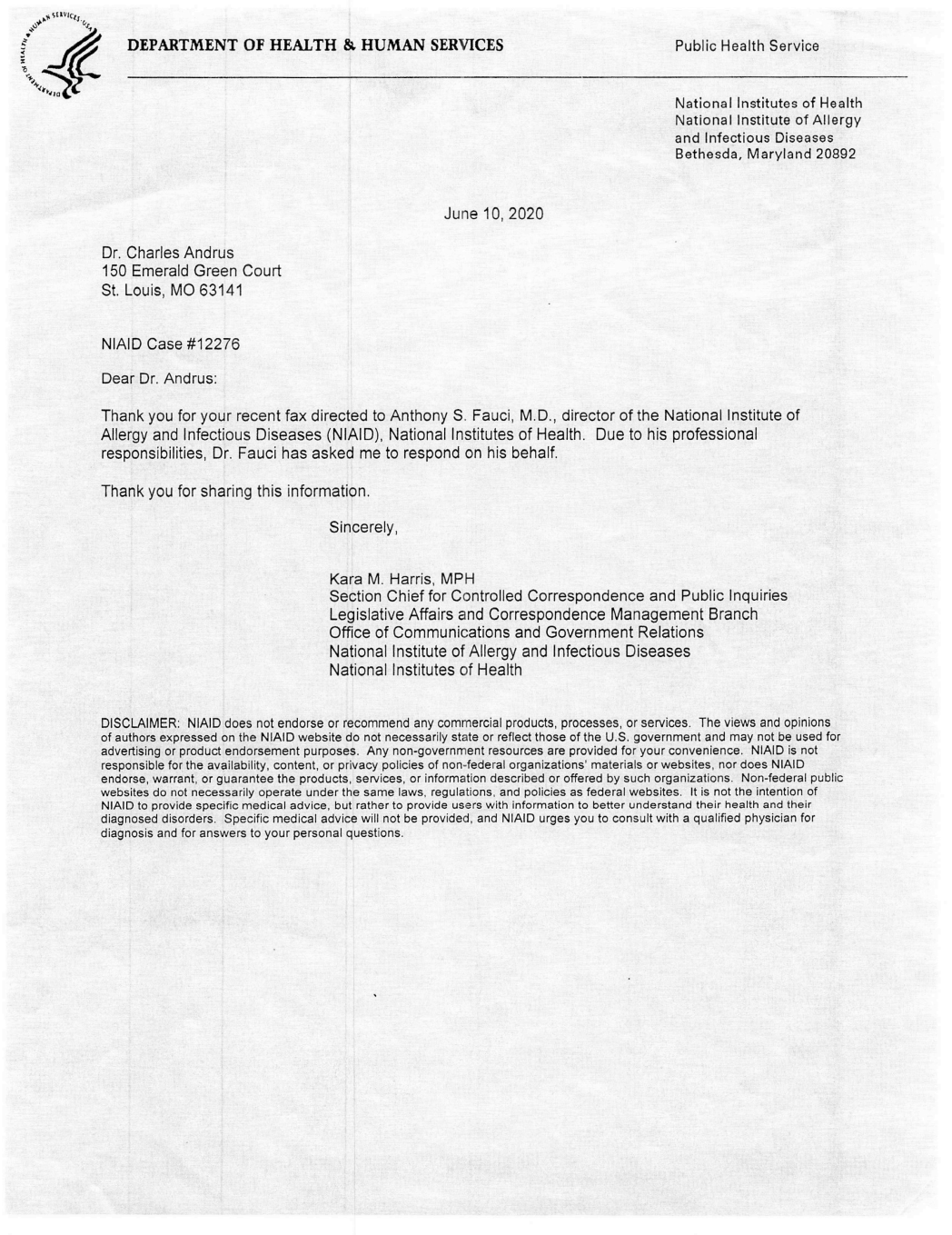
----- May 30, 2022 -----
 This is a COVID-19 Timeline Bibliography for Educational Purposes ONLY in the presentation of this information before the people of the United States³ of America (U.S.A.), the World, and specifically the President of the U.S.A. without any compensation to the author. All submissions including this timeline bibliography can be obtained under the Freedom of Information Act (FOIA) by formally requesting a copy of NIAID Case #12276 from the FIOA Officer of the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health, Bethesda, Maryland

Treatment: *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

Prevention: *Active Immunization:* Vaccines

This submission is NOT for financial gain but for educational purposes only for ALL the American people

Attachment IV Letter²⁴⁰⁻²⁴² establishing NIH, National Institute of Allergy and Infectious Diseases, NIAID case # 12276



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https://www.va.gov/oaa/1400_1hk_Oct2001.doc returns the VA official website which states: **Sorry – we can’t find that page.** Using the Wayback Machine, for 2004-10-28: http://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400_1hk_Oct2001.doc which states on pages 8 – 9:

(3) **Level 3.** The staff practitioner is immediately available in the facility – campus for direct resident supervision according to local policy as approved by the Network Academic Affiliations Officer. The service chief is responsible for periodically reviewing cases done under Level 3 supervision to ensure that such supervision is appropriate.

Using the Wayback Machine another version of the Level 3 Supervision (now Level D) is identified: In VHA Handbook of July 27, 2005 signed by Jonathan B. Perlin, M.D. https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400_1hk_July_27_05.doc (Recission of the previous version of May 3, 2004 which cannot be found):

4. **Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.

Using the only other “hit” on the Wayback Machine of December 21, 2016, http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400_1hk_Oct2001.doc **VHA 1400.1** has been removed completely and in its place is the website of the U.S. Department of Veterans Affairs which states: “Page Not Found.” **De facto, the U.S. DVA, VHA**

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4. Level D: Attending in OR Suite, Immediately Available. The supervising practitioner is physically present in the operative or procedural suite and able to provide direct supervision or consultation without delay as needed. (page 9)

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Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts. https://web.archive.org/web/20140814150238/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

40. Petzel RA: Utilization of Physician Assistants (PA), VHA Directive 1063 (1), Veterans Health Administration, U.S. Department of Veterans Affairs, December 24, 2013. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 which is redirected when accessed to AMENDED June 24, 2024. Captured on July 22, 2023, by the *Internet Archive*. https://web.archive.org/web/20230722070741/https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2958 In **2. SUMMARY OF CHANGES** of the **Transmittal Sheet** which is still labelled **December 24, 2013** but in red has stamped: **AMENDED May 17, 2022** is: (1) Paragraphs 2.c. and 2.e. removes references to the Supremacy Clause reference and physician liability.—which means that the independent practice of a VHA Physician Assistant was rescinded returning all Physicians Assistants to the State Medical Board statutes outlining mandatory Physician scope of practice affiliations and legally mandated Physician oversight. The signatory official on this document is Robert A. Petzel, M.D., Under Secretary for Health who had been terminated over the Phoenix VAMC scandal 8 years prior to this as noted above in references 36 and 37.

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After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired Fighting for Care narrated by Diane Sawyer. 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Temple, TX VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, ABC News PrimeTime Live, for "Fighting for Care," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents— I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Temple TX VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

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Antibodies have been used for a century for the prevention and treatment of infectious diseases (Table 1). In bacterial disease, antibodies neutralize toxins, facilitate opsonization, and, with complement, promote bacteriolysis; in viral disease, antibodies block viral entry into uninfected cells, promote antibody-directed cell-mediated cytotoxicity by natural killer cells, and neutralize virus alone or with the participation of complement.

Prior to the use of antibiotics, antibodies were the only specific agents for the treatment of certain infections. Although this role has largely been supplanted by antibiotics, there still remains a crucial role for antibody in the treatment of certain infectious diseases (Table 1). Since several excellent reviews are available, this article will emphasize new developments (30, 31, 101, 164, 165).

Antibodies can be administered as human or animal plasma or serum, as pooled human immunoglobulin for intravenous (IVIG) or intramuscular (IG) use, as high-titer human IVIG or IG from immunized or convalescing donors, and as monoclonal antibodies (Mab) (30, 164, 178). The therapeutic use of Mab is increasing dramatically, but only one (palivizumab for respiratory syncytial virus [RSV]) has been licensed for prophylaxis of an infectious disease.

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Footnote at bottom of every page of this Annotated Bibliographic Timeline:

----- May 30, 2022 -----
This is a COVID-19 Timeline Bibliography for Educational Purposes ONLY in the presentation of this information before the people of the United States of America (U.S.A.), the World, and specifically the President of the U.S.A. without any compensation to the author. All submissions including this timeline bibliography can be obtained under the Freedom of Information Act (FOIA) by formally requesting a copy of NIAID Case #12276 from the FIOA Officer of the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health, Bethesda, Maryland ³

Treatment: *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

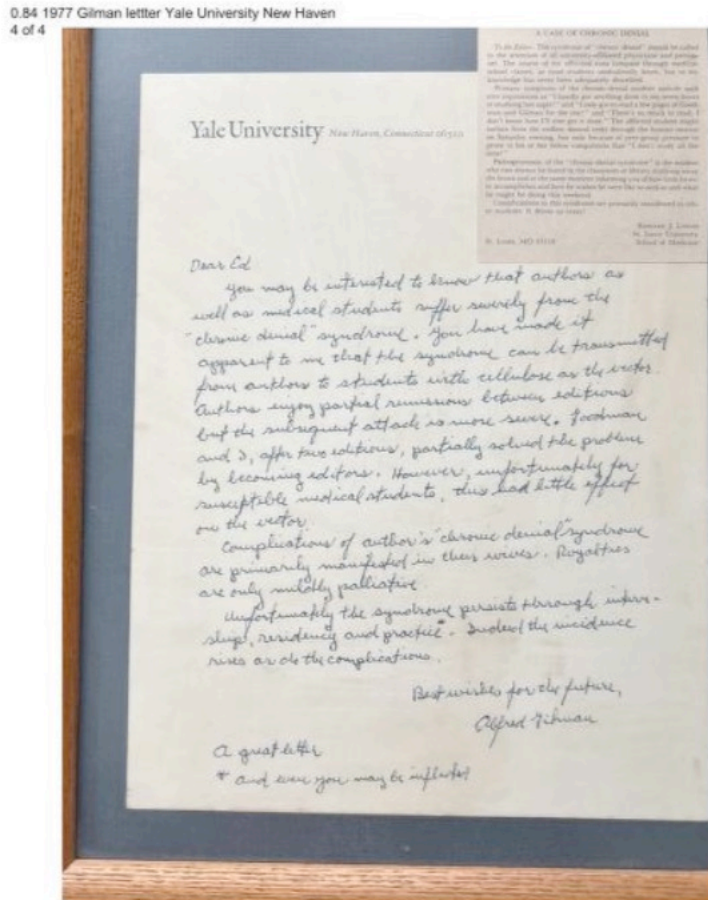
Prevention: *Active Immunization:* Vaccines

This submission is NOT for financial gain but for educational purposes only for ALL the American people

0.6 Attachment V 1977 NEJM letter of Case of Chronic Denial with Alfred Gilman response.docx

Attachment V: Alfred Gilman response letter to the 1977 NEJM letter to the Editor: Case of Chronic Denial²⁴³⁻²⁴⁵

<https://archive.org/details/book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong/page/0/mode/2up> go to page e302 and then the following 5 pages contain the below reproduction and the discussion of this letter from Alfred Gilman, PhD.



Yale University New Haven, Connecticut 06510

Dear Ed

You may be interested to know that authors as well as medical students suffer severely from the "chronic denial" syndrome. You have made it apparent to me that the syndrome can be transmitted from authors to students with cellulose as the vector. Authors enjoy partial remissions between editions but the subsequent attack is more severe. Goodman and I, offer two editions, actually solved the problem by becoming editors. However, unfortunately for susceptible medical students, this had little effect on the vector.

Complications of authors "chronic denial" syndrome are primarily manifested in their wives. Royalties are only mildly palliative.

Unfortunately the syndrome persists through internship, residency and practice.* Indeed the incidence rises as do the complications.

A great letter
*and ever you may be infected

Best wishes for the future,
Alfred Gilman

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https://www.va.gov/oaa/1400_1hk_Oct2001.doc returns the VA official website which states: **Sorry – we can't find that page.** Using the Wayback Machine, for 2004-10-28: https://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400_1hk_Oct2001.doc which states on pages 8 – 9:

(3) **Level 3.** The staff practitioner is immediately available in the facility – campus for direct resident supervision according to local policy as approved by the Network Academic Affiliations Officer. The service chief is responsible for periodically reviewing cases done under Level 3 supervision to ensure that such supervision is appropriate.

Using the Wayback Machine another version of the Level 3 Supervision (now Level D) is identified: In VHA Handbook of July 27, 2005 signed by Jonathan B. Perlin, M.D. https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400_1hk_July_27_05.doc (Recission of the previous version of May 3, 2004 which cannot be found):

4. **Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.

Using the only other “hit” on the Wayback Machine of December 21, 2016, http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400_1hk_Oct2001.doc **VHA 1400.1** has been removed completely and in its place is the website of the U.S. Department of Veterans Affairs which states: “Page Not Found.” **De facto, the U.S. DVA, VHA**

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4. Level D: Attending in OR Suite, Immediately Available. The supervising practitioner is physically present in the operative or procedural suite and able to provide direct supervision or consultation without delay as needed. (page 9)

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Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts.

https://web.archive.org/web/20140814150238/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

40. Petzel RA: Utilization of Physician Assistants (PA), VHA Directive 1063 (1), Veterans Health Administration, U.S. Department of Veterans Affairs, December 24, 2013. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 which is redirected when accessed to AMENDED June 24, 2024. Captured on July 22, 2023, by the *Internet Archive*. https://web.archive.org/web/20230722070741/https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2958 In **2. SUMMARY OF CHANGES** of the **Transmittal Sheet** which is still labelled **December 24, 2013** but in red has stamped: **AMENDED May 17, 2022** is: (1) Paragraphs 2.c. and 2.e. removes references to the Supremacy Clause reference and physician liability.—which means that the independent practice of a VHA Physician Assistant was rescinded returning all Physicians Assistants to the State Medical Board statutes outlining mandatory Physician scope of practice affiliations and legally mandated Physician oversight. The signatory official on this document is Robert A. Petzel, M.D., Under Secretary for Health who had been terminated over the Phoenix VAMC scandal 8 years prior to this as noted above in references 36 and 37.

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After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired Fighting for Care narrated by Diane Sawyer. 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Temple, TX VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, ABC News PrimeTime Live, for "Fighting for Care," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents— I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

0.6 Attachment V 1977 NEJM letter of Case of Chronic Denial with Alfred Gilman response.docx

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Temple TX VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

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Antibodies have been used for a century for the prevention and treatment of infectious diseases (Table 1). In bacterial disease, antibodies neutralize toxins, facilitate opsonization, and, with complement, promote bacteriolysis; in viral disease, antibodies block viral entry into uninfected cells, promote antibody-directed cell-mediated cytotoxicity by natural killer cells, and neutralize virus alone or with the participation of complement.

Prior to the use of antibiotics, antibodies were the only specific agents for the treatment of certain infections. Although this role has largely been supplanted by antibiotics, there still remains a crucial role for antibody in the treatment of certain infectious diseases (Table 1). Since several excellent reviews are available, this article will emphasize new developments (30, 31, 101, 164, 165).

Antibodies can be administered as human or animal plasma or serum, as pooled human immunoglobulin for intravenous (IVIG) or intramuscular (IG) use, as high-titer human IVIG or IG from immunized or convalescing donors, and as monoclonal antibodies (Mab) (30, 164, 178). The therapeutic use of Mab is increasing dramatically, but only one (palivizumab for respiratory syncytial virus [RSV]) has been licensed for prophylaxis of an infectious disease.

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241. Andrus CH: Letter to Dr. Fauci and Dr. Hahn regarding: Time: The Crucial *Independent Variable* of the COVID-19 Pandemic. 2020 June 7 <https://archive.org/details/book-1-dr-mr-president..-covid-19-and-where-we-went-wrong-2023-02-02/page/1150/mode/2up?q=harris>
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0.6 Attachment V 1977 NEJM letter of Case of Chronic Denial with Alfred Gilman response.docx

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2015-09-17 HHS.gov, U.S. Department of Health and Human Services: What is the cost for getting records under the FOIA? <https://www.hhs.gov/foia/faqs/what-is-the-cost-forgetting-records-under-the-foia/index.html>

Footnote at bottom of every page of this Annotated Bibliographic Timeline:

----- May 30, 2022 -----
This is a COVID-19 Timeline Bibliography for Educational Purposes ONLY in the presentation of this information before the people of the United States³ of America (U.S.A.), the World, and specifically the President of the U.S.A. without any compensation to the author. All submissions including this timeline bibliography can be obtained under the Freedom of Information Act (FOIA) by formally requesting a copy of NIAID Case #12276 from the FIOA Officer of the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health, Bethesda, Maryland

Treatment: *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

Prevention: *Active Immunization:* Vaccines

This submission is NOT for financial gain but for educational purposes only for ALL the American people

0.6 Attachment V 1977 NEJM letter of Case of Chronic Denial with Alfred Gilman
response.docx

0.6 Attachment V 1977 NEJM letter of Case of Chronic Denial with Alfred Gilman
response.docx

0.6 Attachment V 1977 NEJM letter of Case of Chronic Denial with Alfred Gilman
response.docx

Attachment VI: Tables regarding Sources, Definitions, and Statistics**Table I: Listing of some of the Sources and Data Bases****General Sources**

Internet Archive and the Wayback Machine.^{246,247} <https://web.archive.org/>
 Perplexity. <https://www.perplexity.ai/>
 OVID, Medline. <https://www.wolterskluwer.com/en/solutions/ovid/ovid-medline-901>
 InterLibraryLoan ILLiad <https://www.slu.edu/library/services/interlibrary-loan.php> (specific per institution)
 PubMed. <https://pubmed.ncbi.nlm.nih.gov/>
 MedlinePlus <https://medlineplus.gov/>
 Our World in Data (OWID) <https://ourworldindata.org/>
 Johns Hopkins Coronavirus Resource Center <https://coronavirus.jhu.edu/>
 Johns Hopkins Bloomberg School of Public Health: Department of Biostatistics.
<https://publichealth.jhu.edu/departments/biostatistics>
 ClinicalTrials.gov. <https://clinicaltrials.gov/>

United States Government Sources and Correspondence with:

U.S. National Archives <https://www.archives.gov/>
 U.S. Department of Veterans Affairs <https://www.va.gov/>
 U.S. Department of Health and Human Services. <https://www.hhs.gov/>
 Food and Drug Administration <https://www.fda.gov/>
 National Institutes of Health. <https://www.nih.gov/>
 National Library of Medicine <https://www.nlm.nih.gov/>
 NCBI, NIH National Library of Medicine, National Center for Biotechnology
 Information <https://www.ncbi.nlm.nih.gov/>
 National Institute of Allergy and Immunology (NIAID)
 [specifically for this paper: **NIAID file # 12276**] <https://www.niaid.nih.gov/>
 CDC <https://www.cdc.gov/>
 MMWR. <https://www.cdc.gov/mmwr/index.html>
 U.S. Department of Homeland Security <https://www.dhs.gov/>
 U.S. Congressional Website <https://www.congress.gov/>
 U.S. Library of Congress <https://www.loc.gov/item/lcwaN0003262/> (previously
https://webarchive.loc.gov/all/*/http://thomas.loc.gov/)
 NCBI-National Institutes of Health. <https://www.nih.gov/>
 Institute of Medicine [IOM] –After April 28, 2015 National Academy of Medicine [NAM]
<https://nam.edu/>
 Federal Depository Library System <https://ask.gpo.gov/s/FDLD>
 The Freedom of Information Act ²⁴⁸⁻²⁵¹

Medical Sources and Communications

American Medical Association <https://www.ama-assn.org/>
 American College of Surgeons <https://www.facs.org/>
 Institute of Medicine (IOM) After April 28, 2015 National Academy of Medicine [NAM]
<https://nam.edu/>

Association American of Medical Colleges (AAMC). <https://www.aamc.org/>
 Accreditation Council for Graduate Medical Education (ACGME). <https://www.acgme.org/>
 Katherine DiAngelis, former Editor, Journal of the American Medical Association
 Philip Drazen, former Editor, The New England Journal of Medicine
 C. Rollins Hanlon, M.D., F.A.C.S., former Chairman, Department of Surgery, Saint Louis
 University School of Medicine; former Executive Director, American College of Surgeons; and
 former *Emeritus* Executive Director, American College of Surgeons
 Vallee William, M.D., F.A.C.S., former Chairman, Department of Surgeon,

Biographies, Historical Non-fiction, and Textbooks

de Kruif P: *Microbe Hunters*. New York: Harcourt, Brace and Company, 1926.
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 Basic & Clinical Immunology
 Fauci A: On Call—A Doctor’s Journey in Public Service
 Haas D: A Badger Book: *Men of Science*, Illustrated by J.L. Pellicer. Racine, Wisconsin:
 Whitman Publishing Company, 1959. Jacobson JM: Immunotherapy for
 Infectious Diseases
 Shulkin D: *It Shouldn’t Be This Hard to Serve Your Country – Our Broken Government and the
 Plight of Veterans*. New York: BBS, PublicAffairs, Hachette Book Group, 2019.
 Colton T: Statistics in Medicine
 Plotkin SA, Orenstein WA, Offit PA, Edwards KM: Plotkin’s Vaccines
 Stites DP, Stobo JD, Wells JV: Basic & Clinical Immunology
 Hillyer CD, Silberstein LE, Ness PM, Anderson KC, Roback JD: Blood Banking
 and Transfusion Medicine, Basic Principles & Practice
 Institute of Medicine of the National Academies: Resident Duty Hours—
 Enhancing Sleep, Supervision, and Safety

 Thorn GW, Adams RD, Braunwald E, Isselbacher KJ, Petersdorf PG: Harrison’s Principles
 of Internal Medicine, Eighth Edition
 Loscalzo J, MD, PhD, Fauci MD AS, Kasper DJ, MD, Hauser SL, Longo DL, Jameson JL MD:
 21st Edition, Harrison’s Principles of Internal Medicine
 Goodman LS, Gilman A: The Pharmacological Basis of Therapeutics, Fifth Edition
 Goodman-Gilman A, Goodman LS, Gilman A: Goodman and Gilman’s The Pharmacological
 Basis of Therapeutics
 Brunton LL, Knollmann BC: Goodman & Gillman’s The Pharmacological Basis of Therapeutics,
 14th Edition
 Johns Hopkins ABX Guide
<https://www.hopkinsguides.com/hopkins/search?st=OSS&catcode=479&q=COVID-19>

 The House January 6th Committee: The January 6 Report. New York: Harper, 2022
<https://www.govinfo.gov/content/pkg/GPO-J6-REPORT/pdf/GPO-J6-REPORT.pdf>

ATTACHMENT VI additional in depth description: Data bases and some other source material used in the development of this paper: In the development of this analysis, an extensive collection of source materials from Medical Publications, Federal and International data bases, and other Media publications was performed. Attachment III

- A. **Center for Systems Science and Engineering (CSSE), Johns Hopkins University of Medicine Coronavirus Resource Center:** COVID-19 Dashboard. 2020 until stopped collecting data as of 03/10/2023.
<https://coronavirus.jhu.edu/map.html> Daily updates can be reviewed using the *Internet Archive Wayback Machine* <https://web.archive.org/> plus entry of the URL: <https://coronavirus.jhu.edu/map.html> which will yield: Saved 53,719 times between March 9, 2020 and October 1, 2024. (example: for August 23, 2020, <https://web.archive.org/web/20200823030510/https://coronavirus.jhu.edu/map.html> there was reported in the United States: 5,576,206 cases and 174,290 deaths)
- B. Ritchie H, Ortiz-Ospina E, Beltekian D, Mathieu E, Hasell J, Macdonald B, Giattino C, Cameron A, Rodas-Girao, Roser M: Coronavirus Pandemic (COVID-19). Daily Excel database (and other formats) of all reporting countries of the World regarding COVID-19 beginning December 31, 2019.
<https://ourworldindata.org/coronavirus>
- C. **Internet Archive:** a 501(c)(3) non-profit, is an ongoing (since 1996) building of “a digital library of Internet sites and other cultural artifacts in digital form.” Location: 300 Funston Avenue, San Francisco, CA 94118, 415-561-6767
<https://archive.org/> As per the website overview <https://archive.org/about/> on October 2, 2024, the *Internet Archive* contains:
- 835 billion web pages
 - 44 million books and texts
 - 15 million audio recordings (including 255,000 live concerts)
 - 10.6 million videos (including 2.6 million Television News programs)
 - 4.8 million images
 - 1 million software programs

For the development of this paper, the following uploads to the Internet Archive are the bulk of background, relevant material:

1. Andrus CH: Book 1: Dear Mr. President: COVID-19 and Where We Went Wrong. Internet Archive publication date: 2023-09-12, pages 1-1266.
<https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02>
2. Andrus CH: 0 2023 9 11 Scan VA RSSO case 286816 Letter Arrived Feb 13 2023. Internet Archive publication date: 2023-09-11. 6 viewable files: 0... pages 1-3; 01... pages 1-10; 3... pages 1-4; 4... pages 1-2; 5... pages 1-

25; 6 <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/0%202023-09-11%20scan%20VA%20RSSO%20Case%20286816%20letter%20arrived%20Feb%2013%202023/>

Six viewable files:

- 0 2023-09-11 scan VA RSSO Case 286816 letter arrived Feb 13 2023.pdf, epages 1-3; <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/0%202023-09-11%20scan%20VA%20RSSO%20Case%20286816%20letter%20arrived%20Feb%2013%202023/>
- 01 2023-01-29 cover Andrus e-mail transmission to VA.pdf, epages 1-10; <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/01%202023-01-29%20cover%20Andrus%20e-mail%20transmission%20to%20VA%20/>
- 3 Appendix C VA Commendations Andrus 2023-01-28.pdf, epages 1-4; <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/3%20Appendix%20C%20VA%20Commendations%20Andrus%202023-01-28/>
- 4 Appendix D Andrus 2023-01-29.pdf epages 1-2; <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/4%20Appendix%20D%20Andrus%202023-01-29/>
- 5 SF-50s including 01-19-2002 45.remarks Constructive Discharge.pdf epages 1-25; <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/5%20SF-50s%20including%2001-19-2002%2045.remarks%20Constructive%20Discharge/>
- 6 1999-11-12 VA OIG report Hines VAH CAP 99-00173-18.pdf epage 1 <https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/6%201999-11-12%20VA%20OIG%20report%20Hines%20VAH%20CAP%2099-00173-18/>
 06.3005 1999 11 22 Hines VAH CAP 99 00173 18 Copy
 Uploaded by Charles H. Andrus, M.D., F.A.C.S. as this VA OIG report was published for PUBLIC RELEASE, by the U.S. Department of Veterans Affairs, Office of Inspector General on November 22, 1999 *but the official VA OIG posting had been subsequently removed from the Internet*. Epages 1-68. <https://archive.org/details/06.3005-1999-11-22-hines-vah-cap-99-00173-18-copy>

3. Andrus CH: Book 3 Abridged Dear Mr President... To Care For Him Who Shall Have Borne The Battle 2024 02 29. Internet Archive publication date: 2024-02-29, epages 1-534. <https://archive.org/details/book-3-abridged-dear-mr-president...-to-care-for-him-who-shall-have-borne-the-battle-2024-02-29>
4. Andrus CH: Book 4 Biden Response to the Summary of Book 1 COVID 19 and Where We Went Wrong. Internet Archive publication date: 2024-02-05 epages 1-848. <https://archive.org/details/book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong/mode/2up> and due to electronic pagination difficulties at e303, this book was again uploaded to as:

Andrus CH: 0.4 Book 4 Biden Response to the Summary of Book 1 COVID 19 and Where We Went Wrong 2nd Attemp Internet Archive publication date: 2024-02-05 epages 1-848. <https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attemp/mode/2up> but still has the same electronic pagination problem of e303-e321 numbered as 0 for each page. From e322 to e466, the pagination is

correctly numbered, and then from e467 the electronic pagination is reset from 1-382 corresponding to the annotated: A COVID-19 Treatment Timeline Bibliography: *Passive Immunization* and *Antiviral Agents* of 1187+ references in chronological order.

D. Library of Congress: There are three documents contained within the uploads to the *Internet Archive* previously submitted and recorder in the U.S. Copyright Office of the U.S. Library of Congress for **preservation for history**:

1. Andrus CH: *Time: The Crucial Independent Variable of the COVID-19 Pandemic*, U.S. Copyright Office, Library of Congress, 2020-06-08, TXu002199029.
https://web.archive.org/web/20210904014401/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=9&ti=1%2C9&Search_Arg=Andrus+Charles+H&Search_Code=NALL&CNT=25&PID=DvTGOW_Qvd_foYxTFRVcdewL3ktMCwz&SEQ=20210425193720&SID=1
2. Andrus CH: *The Mayo Clinic "Safety Update" should be classified as a completed Phase I trial of COVID-19 convalescent plasma*. U.S. Copyright Office, 2020-07-22, TXu002214049.
https://web.archive.org/web/20210904020833/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=6&ti=1%2C6&Search_Arg=andrus+charles+h&Search_Code=NALL&CNT=25&PID=cXfFuGrmHQvLVILvfNNt7Yjwh73ImgQ&SEQ=20210512081428&SID=1
3. Andrus CH: *I Dear Mr President PLEASE COVID-19 Convalescent Plasma NOW 11-17-2020*. U.S. Copyright Office, 2020-11-18, TXu002232947.
https://web.archive.org/web/20210904021628/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=3&ti=1%2C3&Search_Arg=andrus+charles+h&Search_Code=NALL&CNT=25&PID=py6zcjaddPxEbahiUXXmsV0vRNwjXMy&SEQ=20210512081735&SID=2

D. FDA.gov Archive: Throughout the development of this paper, a multitude of publications, press announcements, etc. were accessed. The actual methodology of archiving has changed and thus a verbatim copy of the official description follows.

FDA.gov Archive

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[Email](#)
[Print](#)

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FDA.gov Archive

[Accessibility @ FDA](#)

[Website Policies](#)

FDA [archived web material](#) is maintained within the Pagefreezer platform. FDA.gov first capture on Pagefreezer occurred in May 2021. The content on this site is for historical purposes only and is no longer being updated. The information may be outdated, links may no longer function, and the content may not be compliant with Section 508 of the Rehabilitation Act.

We have kept our captures on the Archive-it platform for historical references. Our last capture on the Archive-It platform was in December of 2020.

1. Go to the [FDA.gov Web Archive page](#) in Archive-It.
2. Click the date for the snapshot you want to view.
3. The FDA.gov home page appears. Browse through the site.

Note that the search function on each page in the FDA.gov Web Archive is disabled. Use the search function above instead.

If you cannot find a page in the FDA.gov Web Archive, you may want to try the [Internet Archive Wayback Machine](#) for FDA.gov. The non-profit Internet Archive has archived some (but not all) of FDA.gov pages and files since 1996.

Content current as of:
08/05/2019

E. NLM, National Library of Medicine: The NLM and its archives have been instrumental in the development of this paper. History of the NLM Collection <https://www.ncbi.nlm.nih.gov/books/NBK518773/> The NIH Almanac: <https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-library-medicine-nlm>

F. Data bases and statistical, and graphic handling

1. Google <https://www.google.com/>;
2. Perplexity <https://www.perplexity.ai/>;
3. Internet Archive Wayback Machine <https://web.archive.org/>;
4. Microsoft Excel version 16.89.1, 2024;
5. StatView 5.0.1 for Macintosh and Windows, release 5.0.1, 1998 March;
6. GraphPad Prism 10 for macOS, version 10.3.0 (461), 2024 July 26, graphpad.com.

G. FDA presentations of August 23, 2020 and September 23, 2020 (Attachment III)

H. 536 letters posted to members of the U.S. Senate and House of Representatives and the President of the United States (Attachment IV)

1. 01 Dear Members of Congress and President Trump 8_23_2020
2. 02 Dear Members of the U.S. House of Representatives 8_28_2020

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2. Penguin Random House: *On Call – Anthony Fauci, M.D.* <https://sites.prh.com/oncall> , <https://web.archive.org/web/20240615140117/https://sites.prh.com/oncall> , June 15, 2024.
3. Abbasi J: Anthony Fauci, MD, on COVID-19, Schools, and Larry Kramer. JAMA.com. JAMA 2020 Jun 8;324(3): 220-222. <https://jamanetwork.com/journals/jama/fullarticle/2767208>
4. Society of Jesus—Religious order founded by Saint Ignatius Loyola. Catholic Answers Encyclopedia <https://www.catholic.com/encyclopedia/society-of-jesus>
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(3) **Level 3.** The staff practitioner is immediately available in the facility – campus for direct resident supervision according to local policy as approved by the Network Academic Affiliations Officer. The service chief is responsible for periodically reviewing cases done under Level 3 supervision to ensure that such supervision is appropriate.

Using the Wayback Machine another version of the Level 3 Supervision (now Level D) is identified: In VHA Handbook of July 27, 2005 signed by Jonathan B. Perlin, M.D. https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400_1hk_July_27_05.doc (Recission of the previous version of May 3, 2004 which cannot be found):

4. **Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.

Using the only other “hit” on the Wayback Machine of December 21, 2016, http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400_1hk_Oct2001.doc VHA 1400.1 has been removed completely and in its place is the website of the U.S. Department of Veterans Affairs which states: “Page Not Found.” **De facto, the U.S. DVA, VHA**

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4. Level D: Attending in OR Suite, Immediately Available. The supervising practitioner is physically present in the operative or procedural suite and able to provide direct supervision or consultation without delay as needed. (page 9)

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Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts.

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40. Petzel RA: Utilization of Physician Assistants (PA), VHA Directive 1063 (1), Veterans Health Administration, U.S. Department of Veterans Affairs, December 24, 2013. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 which is redirected when accessed to AMENDED June 24, 2024. Captured on July 22, 2023, by the *Internet Archive*. https://web.archive.org/web/20230722070741/https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2958 In **2. SUMMARY OF CHANGES** of the **Transmittal Sheet** which is still labelled **December 24, 2013** but in red has stamped: **AMENDED May 17, 2022** is: (1) Paragraphs 2.c. and 2.e. removes references to the Supremacy Clause reference and physician liability.—which means that the independent practice of a VHA Physician Assistant was rescinded returning all Physicians Assistants to the State Medical Board statutes outlining mandatory Physician scope of practice affiliations and legally mandated Physician oversight. The signatory official on this document is Robert A. Petzel, M.D., Under Secretary for Health who had been terminated over the Phoenix VAMC scandal 8 years prior to this as noted above in references 36 and 37.
41. Petzel RA: Utilization of Physician Assistants (PA) VHA Directive 1063(2), December 24, 2013 **AMENDED June 24, 2024**. When one uses a search engine like GOOGLE or enters the official URL of this document site: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 , one is electronically shifted to a .pdf file, e.g.: [file:///Users/andrusmd1/Downloads/1063\(2\)_D_2013-12-24%20\(6\).pdf](file:///Users/andrusmd1/Downloads/1063(2)_D_2013-12-24%20(6).pdf). The <https://...> URL version was captured by the *Internet Archive* on July 18, 2024. The signatory official on this document is still Robert A. Petzel, M.D., Under Secretary for Health, who had been terminated over the Phoenix VAMC scandal 10 years prior to this as noted above in references 36 and 37. https://web.archive.org/web/20240718212213/https://www.va.gov/VHApublishations/ViewPublication.asp?pub_ID=2958
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After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired Fighting for Care narrated by Diane Sawyer. 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Temple, TX VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, ABC News PrimeTime Live, for "Fighting for Care," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents— I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Temple TX VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

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Antibodies have been used for a century for the prevention and treatment of infectious diseases (Table 1). In bacterial disease, antibodies neutralize toxins, facilitate opsonization, and, with complement, promote bacteriolysis; in viral disease, antibodies block viral entry into uninfected cells, promote antibody-directed cell-mediated cytotoxicity by natural killer cells, and neutralize virus alone or with the participation of complement.

Prior to the use of antibiotics, antibodies were the only specific agents for the treatment of certain infections. Although this role has largely been supplanted by antibiotics, there still remains a crucial role for antibody in the treatment of certain infectious diseases (Table 1). Since several excellent reviews are available, this article will emphasize new developments (30, 31, 101, 164, 165).

Antibodies can be administered as human or animal plasma or serum, as pooled human immunoglobulin for intravenous (IVIG) or intramuscular (IG) use, as high-titer human IVIG or IG from immunized or convalescing donors, and as monoclonal antibodies (Mab) (30, 164, 178). The therapeutic use of Mab is increasing dramatically, but only one (palivizumab for respiratory syncytial virus [RSV]) has been licensed for prophylaxis of an infectious disease.

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Footnote at bottom of every page of this Annotated Bibliographic Timeline:

----- May 30, 2022 -----
 This is a COVID-19 Timeline Bibliography for Educational Purposes ONLY in the presentation of this information before the people of the United States³ of America (U.S.A.), the World, and specifically the President of the U.S.A. without any compensation to the author. All submissions including this timeline bibliography can be obtained under the Freedom of Information Act (FOIA) by formally requesting a copy of NIAID Case #12276 from the FIOA Officer of the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health, Bethesda, Maryland

Treatment: *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

Prevention: *Active Immunization:* Vaccines

This submission is NOT for financial gain but for educational purposes only for ALL the American people



150 Emerald Green Court
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314-455-9482

August 23, 2020

Re: Thousands of Americans are *needless dying* because the FDA is illegally ignoring PL 115-176 – *The Right to Try Law*^{1,2} and COVID-19 Convalescent Plasma has NOT been given as Prophylaxis and Early after COVID-19 positivity conversion

Dear Members of the U.S. Congress and President Trump:

By legally, bureaucratic obfuscation and the U.S. Food and Drug Administration (FDA) not officially declaring the Mayo Clinic “Safety Update”³ a ***Completed Phase I study***, the FDA is illegally evading PL 115-176^{1,2} and thousands of Americans are needlessly dying.⁴⁻¹⁰ On March 24, 2020, COVID-19 convalescent plasma was announced by the FDA to the American public:⁴

Convalescent plasma has the potential to lessen the severity or shorten the length of illness caused by COVID-19. This collaboration, involving BARDA, the American Red Cross  and the Mayo Clinic , will allow for a simplified process for health care providers about product efficacy. The FDA anticipates that the effort will be able to move thousands of units of plasma to patients who need them in the coming weeks.

Over the last five months¹⁰, the FDA¹¹⁻¹², The White House¹³, FDA Commission Stephen Hahn, M.D.¹⁴⁻¹⁵, DHHS Secretary Azar¹⁶, and the President^{17,18} have emphasized COVID-19 Convalescent Plasma’s importance in the initial treatment and prophylaxis of COVID-19. Since April 3, 2020 to the present, more than five million Americans have contracted COVID-19 and over 160,000 Americans have died. BUT only 1.2% of the COVID-19 infected population has received COVID-19 convalescent plasma through the National Expanded Access Treatment Protocol.^{10,19} COVID-19 convalescent plasma has been **incorrectly given to only those severely ill** following FDA directed eligibility criteria⁹ rather than to all persons—those severely ill, in early stages of the disease, and prophylactically.⁹ While only 1.2% of the infected COVID-19 population was afforded access to COVID-19 convalescent plasma, when the Chinese came to the aid of the Italians in March 2020, China offered **90 tons of COVID-19 convalescent plasma** to the Italian people.²⁰

90 ~~tons~~ x $\frac{2000 \text{ lbs}}{1 \text{ Ton}}$ x $\frac{454 \text{ g}}{1 \text{ lb}}$ x $\frac{1 \text{ ml plasma}}{1 \text{ g}}$ x $\frac{1 \text{ dose}}{200 \text{ ml}}$ = 408,600 doses COVID-19 convalescent plasma

which came from 204,300 individual donations by Chinese citizens recovered from COVID-19.



The one treatment available when patients first contract COVID-19 and for prophylaxis for people of high exposure: healthcare workers, nursing home patients, prisoners, grocery workers, etc. ***should be* COVID-19 Convalescent Plasma. COVID-19 Convalescent Plasma** should be given to anyone as soon as they become COVID-19 positive or are placed in a high-risk situation

or environment! Short of a self-contained astronaut's suit for individual quarantine and protection, as COVID-19 is a respiratory-transmitted RNA virus, there is no other absolute preventative method with 100% reliability of avoiding contraction of the disease. As COVID-19 is epidemic throughout the general American population and we are all immunologically naïve to the virus if we have not previously contracted it, we **MUST** develop immunity (neutralizing IgG antibodies) over a two-week period either by COVID-19 infection or by vaccination.^{21,22} COVID-19 Convalescent Plasma can provide **Passive Immunization** with neutralizing antibodies from COVID-19 recovered patients to immunologically naïve individuals during the two week interval between immunologic naivete and acquired immunity.

As with all convalescent plasmas, the neutralizing antibodies for a specific disease are conveyed by the administration of convalescent plasma. The concept of **Passive Immunization** for which Dr. von Behring was awarded the first Nobel Prize in Physiology or Medicine in 1901, has gone by (and goes by) many names over the last 130 years²³:

- 1) anti-toxins and antisera (e.g.: hyperimmune globulins for tetanus, rabies, etc.)²⁴
- 2) anti-antigen therapy (e.g.: Rhogam)²⁵
- 3) immunotherapy (e.g.: IVIG)
- 4) convalescent plasma (e.g.: measles, mumps, polio, influenza, SARS, Ebola)²⁶


All above are synonyms / variations of **Passive Immunization** and are well-established as early treatments and prophylaxis in diseases in which the human body is immunologically naïve and there are **no** antibiotic, antiviral, or monoclonal antibody therapies available at the time.²⁷⁻³⁰ Even today, if you have been vaccinated previously with tetanus toxoid in the distant past (>10 years or never at all) and you should step on a nail in a barnyard driving *Clostridia tetani* spores into the plantar space of your foot, you will be given not only a vaccination or booster of tetanus toxoid but also tetanus hyperimmune globulin which is convalescent plasma.²⁴ **Passive Immunization** has been a fundamental teaching in all Internal Medicine and Infectious Diseases courses in all USA medical schools over the last century.³¹⁻³³

By the U.S. Food and Drug Administration (U.S. FDA) designating COVID-19 convalescent plasma “investigational” in March 2020⁴, access to COVID-19 convalescent plasma has been delayed, restricted, and *de facto* rationed to this day--requiring Clinical Research Trials of Phase I (safety) and Phase II/III Efficacy Studies.³⁴ Such a staged Phase I, II, III process is very important in determining any new biologic's safety and subsequent usefulness. Unfortunately, in April 2020, the U.S. FDA immediately implemented a work-around of the entire Clinical Research Trials process by establishing “Expanded Access” (**by FDA definition Expanded Access Use = “Compassionate Use” which means it is outside of an appropriate Clinical Trial**).³⁵ The FDA workaround directs the physician potentially administering COVID-19 Convalescent Plasma to his/her COVID-19 positive patient to a **non-USA governmental site** entitled (and is a hyperlink to): [National Expanded Access Treatment Protocol](#)⁷  that is a process implemented and administrated by the Mayo Clinic. Adjacent to the National Expanded Access Treatment Protocol is a *little box and arrow*  ³⁶ which is a hyperlink/website disclaimer of the U.S. FDA disavowing any responsibility for the National Expanded Access Treatment Protocol³⁶:

Website Disclaimer



Our website has links to many other federal agencies, and, in a few cases, to private organizations, foreign governments and international organizations. You should be aware that:

- This graphic notice, , means that you are leaving the U.S. Food and Drug Administration (FDA) site and entering a non-federal website.
- This external link provides additional information that is consistent with the intended purpose of the FDA site.
- The FDA cannot attest to the accuracy of information provided by this link.
- Linking to a non-federal site does not constitute an endorsement by FDA or any of its employees of the sponsors or the information and products presented on the site.
- You will be subject to the destination site's privacy policy when you leave the FDA site.

According to another U.S. FDA website, the definition of “Expanded Access” is “Compassionate Use.”³⁵ By definition and practice as directed by the U.S. FDA, patient outcomes, morbidities, and mortalities under the title of “Expanded Access”/“Compassionate Use” of any investigational new drug or investigational new biologic do not qualify for Clinical Trials Research process of Phase I, Phase II, or Phase III studies. Thus, Seven very large COVID-19 Convalescent Plasma Programs listed on the NIH ClinicalTrials website³⁷ are not eligible for Phase I, II, III research classification at all!: 1) Tulane University; 2) Rutgers New Jersey Medical School; 3) University of California and affiliated hospitals; 4) University of Massachusetts Medical School; 5) AdventHealth Orlando; 6) the University of Colorado and affiliated hospitals; and 7) the Mayo Clinic Health System and all recruited National Expanded Access Treatment Protocol hospitals throughout the USA (as of 8/13/2020, 2774 Sites, 13,740 physicians enrolled, 93,887 patients enrolled, and 64,050 units of COVID-19 infused).

Why is this so important?--Because by this legally obfuscated, convoluted process the U.S. FDA has (1) continued high-severity eligibility criteria meant for Phase I trials only. Thus, Phase I trials can never be completed with “compassionate use” administration of COVID-19 Convalescent Plasma and has (2) legally circumvented and disregarded the “Right to Try” law^{1,2} (PL 115-176 Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act signed into law May 30, 2018) by never concluding/declaring a “Completed” Phase I trial. Convalescent plasma for the last 130 years has been and should be administered as soon as possible or as prophylaxis for high risk groups (in COVID-19: elderly, diabetics, hypertensive patients, and immunosuppressed patients); cohorted individuals (e.g.: nursing home patients, dorm and military personnel, prisoners, etc.); and individuals at high risk of exposure (e.g.:

healthcare personnel, first-responders, and persons with public contact and exposure). As the National Expanded Treatment Protocol continues indefinitely in place, “Expanded Access” **INAPPROPRIATELY** relegates the administration of COVID-19 Convalescent Plasma only to hospitalized patients with life-threatening associated presentations⁹:

Patient Eligibility

To facilitate requests for eINDs for use of COVID-19 convalescent plasma to treat patients, health care providers seeking an emergency IND may want to consider the eligibility criteria used for the [National Expanded Access Treatment Protocol](#). These criteria include:

- Laboratory confirmed COVID-19
- Severe or immediately life-threatening COVID-19, for example,
 - Severe disease is defined as one or more of the following:
 - shortness of breath (dyspnea),
 - respiratory frequency $\geq 30/\text{min}$,
 - blood oxygen saturation $\leq 93\%$,
 - partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300 ,
 - lung infiltrates $> 50\%$ within 24 to 48 hours
 - Life-threatening disease is defined as one or more of the following:
 - respiratory failure,
 - septic shock,
 - multiple organ dysfunction or failure
- Informed consent provided by the patient or healthcare proxy.

In the St. Louis *Post-Dispatch* August 12, 2020, one of the National Expanded Access Treatment Protocol investigators implied “volunteer” patient coercion is appropriate in ongoing Phase II/III studies³⁸:

Since April, the Trump administration has set aside **more than \$300 million** to collect plasma and, with the Mayo Clinic, launch an experimental drug program, serving high-risk patients with few other treatment options. More than 60,000 have received plasma.

But the program has also had an unintended consequence: Patients aren’t signing up for controlled trials, which compare outcomes for patients randomly assigned to receive the treatment with those who receive a placebo.

“If you have a 50% chance of getting either the stuff or nothing, which would you choose?”

It is very unlikely that any Institutional Review Board (IRB) would agree to such an eligibility mandate with implied coercion which is 1) contrary to the voluntary autonomy of Clinical

Research Trial participants and 2) considered unethical. Ironically, all IRBs in the USA are legally overseen by the U.S. FDA.³⁹

Between April 3, 2020 and August 17, 2020, in the National Expanded Access Treatment Protocol, the Mayo Clinic reports 66,735 units of COVID-19 Convalescent Plasma infused.⁴⁰ Between this same interval, 5,162,110 Americans have contracted COVID-19 and 164,439 Americans have died.¹⁹ **How many of those that have died could have had their clinical course muted and possibly death prevented by the early administration of COVID-19 Convalescent Plasma?—We will never know.** On August 17, 2020, it is reported that 1,865,580 Americans have recovered.¹⁹ Each recovered individual could donate by plasmapheresis twice a week yielding 4 units of COVID-19 Convalescent Plasma per week—If all those individuals donated twice, 7.5 million units of COVID-19 Convalescent Plasma could be collected! With regards to directing the collection, processing, and distribution of COVID-19 Convalescent Plasma, this is accomplishable through the AABB⁴¹ if fully-directed, responsibly by the Federal Government through the U.S. FDA. **The Federal Government needs to again become the responsible National Leader** as is mandated by Federal law and promised to the American people--not emboldening privatization and encouraging a disorganized cabal of political and business factions whose only goals are grabbing the glory, encouraging partisan politics, making money, and **putting American lives last in priority.** A visible National Drive in the collection and distribution of COVID-19 Convalescent Plasma should be initiated immediately akin to FDR and President Eisenhower regarding polio^{42,43}; JFK and phenylketonuria⁴⁴, and Gerald Ford and the first flu vaccine⁴⁵. Nothing short of this will be successful! Nothing short of this will be effective!

Attached is a letter entitled: ***The Mayo Clinic “Safety Update” should be Classified as a Completed Phase I Trial of COVID-19 Convalescent Plasma*** sent to Drs. Fauci and Hahn on July 22, 2020 and acknowledged in receipt by the U.S. FDA on July 30, 2020. While it has been submitted twice to the Copyright Office for registration so it can be available to all Members of Congress through the Library of Congress, it has yet to be registered and posted. Thus, I will submit this directly to all the members of Congress individually in the hope that someone will read this material, think about it, and act responsibly. (This with attached letter to Drs. Fauci and Hahn will be submitted to the U.S. Copyright Office of the Library of Congress so it will be available to all Americans. ***I, Charles H. Andrus, M.D., F.A.C.S., waive and turnover all my copyright “rights” to the United States of American and all its people. Please reprint in any format the reader wishes to utilize!***)

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.
Professor, Department of Surgery, Saint Louis University School of Medicine

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August 28, 2020

Re: This is a cover letter to the Congressional Staffer who will initially read the attached packet. After you read this cover letter, please bring it to your Chief of Staff so he or she might assess the importance of showing it to the Congressman or Congresswoman for whom you work.

Dear Member of the U.S. House of Representatives:

As a representative of your Congressional District's constituency, you have been hoodwinked by the FDA, the NIH, and the DHHS; the scientific clinical research community; and the insurance and the pharmaceutical companies regarding COVID-19 Convalescent Plasma.

1. The FDA and the Presidential Coronavirus Taskforce has publicly acknowledged COVID-19 Convalescent Plasma for the last 5 months. They have known that China in aid to Italy in March offered 90 tons of COVID-19 Convalescent Plasma to the Italians. If the physicians on the Presidential Coronavirus Taskforce took their textbooks from medical school off their shelves and read them, they would find sections and chapters on Passive Immunization and its uses as antitoxins, antiserums, anti-Rh-D antibody (Rhogam), rabies vaccine, etc. which have been used successfully for 130 years and its discovery awarded the Nobel Prize in Medicine or Physiology in 1901.

2. By the FDA in March 2020 declaring COVID-19 Convalescent Plasma ***Investigational***:

A. The FDA developed "eligibility criteria" that was meant for Phase I Clinical Trials (only when patients' are at death's-door) for the National Expanded Access Treatment Protocol. COVID-19 Convalescent Plasma has NOT been administered appropriately at the onset of COVID-19 positivity nor prophylactically to high exposure and high-risk individuals.

B. With FDA establishing the National Expanded Access Treatment Protocol for this ***Investigational biologic***, the FDA has used a quirk in their definition of "Expanded Access" to limit administration of COVID-19 Convalescent Plasma to "Compassionate Use Only." ***"Compassionate Use" means that any outcomes from administration cannot be used to "Complete" a Phase I Clinical Trial and thus the >70,000 administrations given through the National Expanded Access Treatment Protocol are useless in Completing a Phase I study and the "Right to Try" law (PL 115-176) cannot take effect.*** Thus, no American who newly converts to COVID-19 positivity can presently receive COVID-19 Convalescent Plasma.

3. On July 30, 2020, at the American Red Cross, the President was briefed on COVID-19 Convalescent Plasma. Such a visit makes it look like he was just then being introduced to the concept of COVID-19 Convalescent Plasma. Three weeks later on August 23, 2020 at 5:30 EDT, the President in a White House press conference proclaimed a "National Emergency" thus permitting the FDA to circumvent the Phase I "Completion" requirement regarding an ***Investigational drug or biologic*** and thus avoid addressing the "Right to Try" law (PL 115-176). There were two subsequent possibilities:

A. If such a plan was immediately implemented, the President would become the immediate hero as no one else—the FDA, the Congress, etc. —has championed COVID-19 Convalescent plasma before the American public —OR—

B. As has happened, the Scientific Research Community is calling for "Efficacy Research" without a "Completed" Phase I Study so the "Right to Try" law (PL 115-176) is circumvented. With a disease that has a finite mortality rate like COVID-19, to persist in Phase II/Phase III efficacy research trials **with Placebo Control groups is unethical!** When COVID-19 Convalescent Plasma is recognized as the only treatment in early COVID-19 positivity and for prophylaxis, the President again becomes the hero as he championed COVID-19 Convalescent

Plasma first – **even though it is five months after the FDA and the Presidential Coronavirus Taskforce acknowledged COVID-19 Convalescent Plasma’s importance, and now it is at least six weeks after the European Union has committed to \$340 million Euros for the collection and distribution of COVID-19 Convalescent Plasma.**

4. Other Ramifications:

A. As COVID-19 is still classified as ***Investigational***, most Health Insurance companies will not pay for it.

B. While Congress passed legislation in March authorizing some free COVID-19 testing of individuals, it did not authorize free testing of donated COVID-19 Convalescent Plasma (a blood product for transfusion) thus at least \$1000 will be added to the cost of COVID-19 Convalescent Plasma dose which will not be paid for by Insurance Companies as it is still classified as ***Investigational***.

C. The NIH, the NCI, and the FDA and all Phase II/III Clinical Trials can maintain the *status quo* of requiring **Placebo Controls** in the face of COVID-19 Convalescent Plasma being the **ONLY** treatment at present-- **THIS** is coercion of “Volunteer Subjects” as stated in 3,B above which is **Unethical**. No Institutional Review Board (IRB) of any repute would approve of such a dilemma in Clinical Research **BUT** the oversight of all IRBs in this country is the U.S. Food and Drug Administration (FDA).

D. All authoritative research scientists calling for more “efficacy” research supporting **Placebo Controls** are actually calling for and condoning withholding of a therapeutic agent from 50% of the American “subjects” akin to the U.S. Public Health Service’s Tuskegee Syphilis project from 1932 to 1972 in which Penicillin was withheld from 399 African-American men with syphilis. Such “authoritative” scientific spokesmen have an inherent “conflict of interest” which is in direct inconsistency with the intent of the “Right to Try” law (PL 115-176). The unspoken dilemma is that with the “Right to Try” law (PL 115-176), patients with potentially life-threatening illnesses once a Phase I safety-study is “Completed” should be able to receive any drug or biologic outside of Phase II/Phase III clinical trials without coercion of participation in **Placebo control-based clinical trials**. As such, application of the “Right to Try” law (PL 115-176) *de facto* MANDATES that all Phase II/III/IV Clinical Trials under the auspices of the U.S. Department of Health and Human Services (NIH, NCI, FDA, PHS, etc.) need to be revised, reapproved by IRBs, and that will cost billions of dollars, Euros, etc. **In short, THE RESEARCH COMMUNITY NEVER WANTS the Right to Try Law (PL 115-176) to be implemented and applied!**

E. While the Research Community never wants the Right to Try law (PL 115-176) to be applied, the Pharmaceutical Industry has taken full advantage of its implications by advertising expensive non-insurance-covered drugs and biologics on TV by stating to the public: “Ask your doctor if _____ is right for you.”

5. **In short, the American public has been disingenuously misinformed for five months regarding COVID-19 Convalescent Plasma.** All seats of Members of the U.S. House of Representatives are up for reelection on November 3, 2020. **ALL incumbents running for reelection –Republicans, Democrats, and Independent – have been posed with dilemmas that have essentially “thrown them all under the bus” by the FDA, the NIH, the Health Insurance companies, the Pharmaceutical Industry, and the President! For without Congressional action regarding COVID-19 Convalescent Plasma immediately, more Americans will continue to die without access to the one known therapy available at present in the early treatment and prophylaxis of COVID-19!**

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.
Professor, Department of Surgery
Saint Louis University School of Medicine

The following was submitted to President Biden in September 2021 and uploaded to the *Internet Archive* on February 12, 2023, within: *Book 1: Dear Mr. President: COVID-19 and Where We Went Wrong*. 08 076.0 2021-09-19 Tragedy of Electronic Overwriting copy.docx. *Internet Archive*, Date of Publication: 2023-09-12. Pages e147 through e155.

<https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02/page/147/mode/1up> Following is an edited reproduction of pages e147 through e155, with then a more detailed discussion of electronic overwriting; concealing, changing, and removing URLs; and the lack of integrity in the implementation of these paltering methodologies.

5.0 2021-09-19: THE TRAGIC METHODOLOGY OF ELECTRONIC OVERWRITING OF OFFICIAL GOVERNMENT DOCUMENTS IS AN OBSTRUCTION OF JUSTICE

Dear Mr. President:

Please forgive my forwardness of this cover letter of the documentation I will be presenting to you. Over the last 18 months I have submitted documentation with the U.S. Department of Health and Human Services through the office of the NIAID of the National Institutes of Health, the Office of the Commissioner of the FDA, and many other federal offices including the Office of the President of the United States with little response to my advocacy. As a federal physician of 24 years of service in the Veterans Health Administration (VHA) of the U.S. Department of Veterans Affairs, it is my duty to bring to your attention that which has collectively been detrimental to the people of the United States of America. While my past focus has been to promote **Passive Immunization** methodologies in the early treatment (<72 hours from diagnosis) of COVID-19 (e.g.: Convalescent Plasma, Convalescent Sera, Monoclonal Antibodies, and Monoclonal Antibody cocktails), the most glaring foundational problem common to our addressing the coronavirus SARS-CoV-2 has been harmful **selective transparency**, misdirection, **obfuscation**, and lies promoted by U.S. Medicine, U.S. Medical Research, U.S. Pharma, and agencies of the Executive Branch of the Federal Government (e.g.: FDA, NIAID, NIH, CDC, USPHS, VHA of the DVA, etc.). By (1) altering their adherence to their own-stated policies and directives; (2) violating or negating public laws: e.g.: EMTALA, PL-89-97 and The Right to Try Act, PL-115-176; and (3) misinterpreting fundamental immunology concepts; (4) misapplying and ignoring research ethics as proclaimed by the Nuremberg Code, the Helsinki Accords, and the Belmont Report; (5) redefining incorrectly key medical terminology, and (6) misrepresenting the very definitions promoted by the U.S. Department of Health and Human Services: e.g.: Clinical Trials, placebos, EUA, Expanded Access, and the very foundational Congressionally-mandated decrees establishing the FDA (over a century ago), U.S. Medicine and the U.S. Government have synergistically **failed the American people!**

Attached to this cover letter are multiple aspects of where we, as the U.S.A. in the fight against COVID-19 went wrong. Below is the latest personal example that was presented to my family by my wife purchasing two of the at-home COVID-19 Antigen Self tests: Abbott's BinaxNOW and Quidel's QuickVue. Both contain the following statement (with slight variations):

This product has not been FDA cleared or approved, but has been authorized by the FDA under an Emergency Use Authorization (EUA) for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens...

Except for Remdesivir (VELKURY, NDA #214787, October 22, 2020) and Pfizer's COVID-19 vaccine (COMIRNATY, BL 125742/0, August 23, 2021), all other agents being utilized in the fight of COVID-19 for testing, treatment, and prevention of COVID-19 are under Emergency Use Authorizations (EUAs) which mean they are all "*Investigational*" or in Medical Research terminology: **Experimental**. We, as a nation, have given out over 200 million doses of vaccines (**Active Immunization**) under the auspices of **Medical Research experimentation** during this pandemic.—It is no wonder that a large percentage of the American people still refuse to be vaccinated with these "Experimental Agents." The generic term

Passive Immunization (Convalescent plasma/sera and monoclonal antibodies) has never been mentioned to the American public even though ~722,000 units of COVID-19 convalescent plasma/sera have been administered over the last 18 months **AT THE WRONG TIME late in the course of the disease!**

Normally, in NIH authorized Clinical Trials and in policies of the FDA, successful completion of a phase 1 trial with regards to safety is met when approximately 20 – 40 individuals with the disease have had minimal side-effects attributable to the Investigational agent when administered. When efficacy has been demonstrated in Phase 2/3 studies (200-400 individuals) then an agent usually receives FDA approval as a new drug or biologic. Over the last 18 months, hundreds of thousands of these agents of Active and Passive Immunization have been given out by hospitals, infusion centers, and other emergency sites under the auspices of EUAs—Experimental Administrations.

While someone purchasing the OTC tests mentioned above assumes they are screening tests for SARS-CoV-2 antigens in the nares of an individual, **neither meets medical sensitivity significance criteria** for a screening test of 2 standard deviations from the mean (a 95% confidence level): Abbott's BinaxNOW 91.7% sensitivity and Quidel QuickVue At-Home OTC COVID-19 Test of 83.5% sensitivity. **Most of all Mr. President**, while both tests within their packaged directions states that the reagents of the test can be harmful if contacted by an individual, NO WHERE is it stated the legal FDA warning of: KEEP OUT OF REACH OF CHILDREN (21 CFR 369.9) on the packaging. I chose this example because it presents minor lapses of dereliction to duty by the FDA when overall there have been major infractions by the FDA and the NIH.

Throughout the last 18 months, both the FDA and NIH have disregarded or conveniently overlooked the intent, if not the letter-of-the-law, regarding generic adherence and protection of patients' rights (and more specifically, they ignored PL-115-176, The Right to Try Act at every turn) which, in some circumstances, may have been illegal but, in all instances, violated the collective trust of the American people. Collectively, shame on U.S. Medicine and shame on the agencies of the U.S. Department of Health and Human Services! They should all apologize to the U.S. people!

Mr. President: As Dr. Fauci, you, and I grew up in the era of the Roman Catholic Latin Mass, we of U.S. Medicine and the Executive Branch of the U.S. Government should all be beating our breasts and stating: Mea Culpa, Mea Culpa, Mea Maxima Culpa. In the attached documentation, I will try to explain the following:

1. My summarization of the natural course of the disease of COVID-19 caused by the coronavirus SARS-CoV-2 including:
 - a. The size of the coronavirus SARS-CoV-2 (50 – 140 nm) and its implications regarding N95 masks (there are no true antiviral masks and N95 masks inhibit 95% of particles less than 300 nm in size). <https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/> and <https://www.news-medical.net/health/The-Size-of-SARS-CoV-2-Compared-to-Other-Things.aspx>
 - b. The implications of the longitudinal graphs of daily new cases of COVID-19 and daily deaths attributable to COVID-19. <https://ourworldindata.org/coronavirus> Mr. President, did you know that the graphs of the decline of new cases and new deaths represent logarithmic decays that approach zero daily cases and deaths asymptotically?
 - c. As we have not until this summer officially treated early (before the cytokine cascade and the bradykinin storm late phase) COVID-19 with passive immunization (monoclonal antibodies), one can mathematically define the natural untreated death rate of COVID-19 patients. The derived equations and graphs from the CDC weekly reports regarding mortality by age groups are the following <https://web.archive.org/web/20210217175653/https://www.cdc.gov/nchs/nvss/vsrr/covid-weekly/index.htm#SexAndAge> :

0 – 45 years

$y = 0.0008x - 0.0103$

$R^2=0.8254$

46 - >85 years

$$y = 0.0049x - 0.1216 \quad R^2=0.9972$$

From 4/2020 to present:

Age Range	<u>Mortality %</u> Infected	<u>Deaths by Age Group</u> 100,000 in that Age Group
0 – 17 yrs	0.05%	50 / 100,000
18 – 29 yrs	0.41%	410 / 100,000
30 – 39 yrs	1.19%	1,190 / 100,000
40 – 49 yrs	3.10%	3,100 / 100,000
50 – 64 yrs	15.47%	15,470 / 100,000
65 – 74 yrs	21.63%	21,630 / 100,000
75 – 84 yrs	27.06%	27,060 / 100,000
≥ 85 yrs	31.09%	31,090 / 100,000

2. The chronology of what went wrong in the implementation of Passive Immunization from January 2020 to the present.
3. It would be my suggestion along with your present COVID-19 White House Task Force members, you might invite to the White House for an educational informational session for you the following physicians and present and former governmental individuals:

Francis S. Collins, M.D.; Anthony Fauci, M.D.; Stephen Hahn, M.D.; Janet Woodcock, M.D., Debroah Birx, M.D.; Peter Marx, M.D.; RADM Denise M. Hinton, RN, MS; Michael Joyner, M.D.; Arturo Casadevall, M.D.; Liise-anne Pirofski, M.D.; Jay Epstein, M.D.; Louis M. Katz, M.D.; Leonard Schleifer, M.D.; George Yancopoulos, M.D.; Eric J. Rubin, M.D.; Philip Drazen, M.D.; Howard Bauchner, M.D.; Catherine D. DeAngelis, M.D.; Jeffrey P. Henderson, M.D.; Bruce Hall, M.D.; Steven L Liebman, M.D., Richard Stone, M.D. as a legal counsel representative: Jeffrey Rosen, J.D. (former acting Attorney General from December 23, 2020 to January 20, 2021.); representatives from the Association of American Blood Banks (AABB) and the American Red Cross, Dawn O'Connell, J.D., Assistant Secretary for Preparedness and Response, DHHS; etc.

4. What could be on the agenda for such a meeting:
 - a. A short course in Clinical Immunology regarding the differences between Active and Passive Immunization presented to the President of the United States and how these agents should be utilized synergistically to end the COVID-19 epidemic in the U.S.A.
 - b. Discussion of how to educate the America public and organize infusion centers around the nation for the EARLY administration of Passive Immunization (Convalescent Plasma, Convalescent Sera, Monoclonal Antibodies, and Monoclonal Antibody Cocktails) and Antiviral agents like Remdesivir. Discussion on how to provide the early administration of Passive Immunization throughout the country. Discuss how to mobilized the nation's blood bank to collect and distribute large quantities of COVID-19 convalescent plasma Fresh Frozen plasma (FFP) as was done during WWII administered initially administrated by Charles Drew, M.D., FACS and the by Eleanor Roosevelt. (Today, in one week, literally with 20 donations daily of COVID-19 Convalescent Plasma (CCP) to the >5000 blood banks throughout the U.S.A., 700,000 units of convalescent FFP can be generated. As there are two doses of 200 ml of "high dose" CCP per FFP unit, 1.4 million units per week are possible. If the FFP is "low dose", doubling the volume to a full unit of FFP (400 ml) will double the polyclonal antibodies administered to an individual (e.g.: 2 or 3 x low dose = one high dose unit of CCP) Most of all, on August 23, 2020 using data from approximately 94,000 units administered late in the disease (the wrong time) by the Mayo Clinic/FDA Expanded Access program (compassionate use of which the data should not have been used) the FDA **still concluded that "high dose" was better than "low dose" CCP**. Mr. President, would it not seem reasonable that "high dose" is better than NO DOSE!

- c. Mr. President, with the mortality calculations regarding children under the age of 12 derivable from 1c above, **should a school holiday be declared until such time as all the children can be vaccinated?** Right now we are essentially putting our unvaccinated children who have not contracted previously COVID-19—thus, being individually immunity naïve to COVID-19—in harms way.

Using the equation: $y = 0.0008x - 0.0103$ $R^2=0.8254$

One can calculate the estimated mortality by year per 100,000/infected.

(But by the least square fit equation derived from the CDC data of 0 – 45 years, the predicted age range mortalities really predicts finite mortality from age 13 years and above)

Age	<u>Mortality %</u> Infected	<u>Deaths by Age Group</u> 100,000 in that Age Group
4 yrs	0.71%	0
5 yrs	0.63%	0
6 yrs	0.55%	0
7 yrs	0.47%	0
8 yrs	0.39%	0
9 yrs	0.31%	0
10 yrs	0.23%	0
11 yrs	0.15%	0
12 yrs	0.07%	0
13 yrs	0.01%	10
14 yrs	0.09%	90
15 yrs	0.17%	170
16 yrs	0.25%	250
17 yrs	0.33%	330
18 yrs	0.41%	410
19 yrs	0.49%	490

- d. Discussion of the endpoints regarding full approval of all the agents under EUAs that have demonstrated efficacy by appropriate studies (NOT CCP GIVEN LATE IN THE DISEASE AND LACKING AGE STRATIFIED). The FDA can designate as full-fledged drugs and biologics in the treatment of COVID-19 all the present Passive and Active Immunization agents being utilized by sheer numbers of administrations of these agents over the last 18 months when they were give early (<72 hours after diagnosis) and when analyzed by age-stratification!

Mr. President, by now you are probably wondering how we got into this mess. Well, frankly, it was a lot of little errors or presentations of selective transparency that cascaded in misleading and misdirecting U.S. Medicine and the US government.

1. The worst error was constructing administration criteria for CCP and Remdesivir at “deaths-door” rather than within 72 hours of diagnosis. On March 24, 2020, the following FDA announcement based on a misinterpretation of a February 2020 Chinese epidemiology paper published in JAMA which never speaks of treatment of COVID-19 was issued that set into motion administration of CCP at the WRONG TIME, initiated a multitude of NIH clinical trials based on the WRONG TIME, and initiate Clinical Practices of administration of CCP at the WRONG TIME that even now have not been rescinded in practice!:

Investigational COVID-19 Convalescent Plasma - Emergency INDs

March 24, 2020

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-ind>s

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from public health threats including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to doing everything we can to provide timely response efforts to this pandemic and facilitate access to investigational drugs for use in patients with serious or immediately life-threatening COVID-19 infections.

One investigational treatment being explored for COVID-19 involves the use of convalescent plasma collected from recovered COVID-19 patients. It is possible that convalescent plasma that contains antibodies to SARS-CoV-2 (the virus that causes COVID-19) might be effective against the infection. Use of convalescent plasma has been studied in outbreaks of other respiratory infections, including the 2009-2010 H1N1 influenza virus pandemic, 2003 SARS-CoV-1 epidemic, and the 2012 MERS-CoV epidemic. Although promising, convalescent plasma has not been shown to be effective in every disease studied. It is therefore important to determine through clinical trials, before routinely administering convalescent plasma to patients with COVID-19, that it is safe and effective to do so. Investigators wishing to study the use of convalescent plasma are encouraged to submit requests to FDA for investigational use under the traditional IND regulatory pathway (21 CFR 312).

Although participation in clinical trials is one way for patients to obtain access to convalescent plasma, these may not be readily available to all patients in potential need. Therefore, given the public health emergency that the expanding COVID-19 outbreak presents, while clinical trials are being conducted, FDA is facilitating access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of single patient emergency Investigational New Drug Applications (eINDs) for Individual patients under 21 CFR 312.310. This process allows the use of an investigational drug for the treatment of an individual patient by a licensed physician upon FDA authorization. This does not include the use of COVID-19 convalescent plasma for the prevention of infection.

Healthcare providers interested in the emergency use of investigational COVID-19 convalescent plasma under a single patient emergency IND should consider the following:

- **COVID 19 Convalescent Plasma**

COVID-19 convalescent plasma must only be collected from recovered individuals if they are eligible to donate blood (21 CFR 630.10, 21 CFR 630.15). Required testing must be performed (21 CFR 610.40) and the donation must be found suitable (21 CFR 630.30).

Additional considerations for donor eligibility should be addressed, as follows:

- Prior diagnosis of COVID-19 documented by a laboratory test
- Complete resolution of symptoms at least 14 days prior to donation
- Female donors negative for HLA antibodies or male donors
- Negative results for COVID-19 either from one or more nasopharyngeal swab specimens or by a molecular diagnostic test from blood. A partial list of available tests can be accessed at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>.
- Defined SARS-CoV-2 neutralizing antibody titers, if testing can be conducted (e.g., optimally greater than 1:320)

The container label of COVID-19 convalescent plasma units must include the following statement, "Caution: New Drug-- Limited by Federal (or United States) law to investigational use." (21 CFR 312.6 (a))

- **Eligible patients for use under expanded access provisions:**

- Must have laboratory confirmed COVID-19
- Must have severe or immediately life-threatening COVID-19, for example:¹
 - Severe disease is defined as:
 - dyspnea,
 - respiratory frequency $\geq 30/\text{min}$,
 - blood oxygen saturation $\leq 93\%$,
 - partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300 , and/or
 - lung infiltrates $> 50\%$ within 24 to 48 hours
 - Life-threatening disease is defined as:
 - respiratory failure,
 - septic shock, and/or
 - multiple organ dysfunction or failure
- Must provide informed consent

How to obtain authorization for use of COVID-19 convalescent plasma

- For request that are not highly time sensitive (response from FDA provided within 4 to 8 hours), the requesting physician may contact FDA by completing form 3926 (<https://www.fda.gov/media/98616/download>) and submitting the form by email to CBER_eIND_Covid-19@FDA.HHS.gov.
 - The completed form should include a brief clinical history of the patient, including: diagnosis, current therapy, and rationale for requesting the proposed investigational treatment in order to meet the expanded access use requirements of 21 CFR 312.305 and 312.310.
 - The form should include information regarding where the COVID-19 convalescent plasma will be obtained.
 - Providers should complete the form to the extent possible, and FDA will work with the provider if additional information is required.
 - FDA will review the request and, upon approval, FDA will send the requesting physician a confirmatory email that includes the emergency IND number.
- In the event of an emergency that is highly time sensitive (response required in less than 4 hours) or where the provider is unable to complete and submit form 3926 due to extenuating circumstances, the provider may contact FDA's Office of Emergency Operations at 1-866-300-4374 to seek verbal authorization.
 - If verbal authorization is given, the requestor must agree to submit an expanded access application (e.g., form 3926) within 15 working days of FDA's authorization of the use.

In addition to the above, FDA is continuing to work with its government partners including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to develop master protocols for use by multiple investigators in order to coordinate the collection and use of COVID-19 convalescent plasma.

1Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72,314 Cases From the Chinese Center for Disease Control and Prevention. JAMA. Published online February 24, 2020. doi:10.1001/jama.2020.2648

Content current as of:
03/24/2020

A British Medical Journal article: <https://www.bmj.com/content/bmj/368/bmj.m1256.full.pdf> of March 26, 2020 documented for the world this announcement with it attached three references:

- 1 FDA. Investigational covid-19 convalescent plasma—emergency INDs. <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber-investigational-covid-19-convalescent-plasma-emergency-ind> (When one attempts to use the Wayback machine to find this site, the response is Wayback Machine has not archived that URL.)
- 2 Hixenbaugh M. FDA will allow doctors to treat critically ill coronavirus patients with blood from survivors. NBC News 2020 Mar 24. www.nbcnews.com/news/us-news/fda-will-allow-doctors-treat-critically-ill-coronavirus-patients-blood-n1167831 which contains the hyperlink: *emergency protocols approved by the FDA* which directs to: <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-applications-inds-cber-regulated-products/recommendations-investigational-covid-19-convalescent-plasma> (the February 11, 2021 which is the Wayback Machine first “captured”. ****Need to research this more as previous with the Wayback Machine pointed to April 8, 2020)
- 3 Palca J. FDA expedites treatment of seriously ill covid-19 patients with experimental plasma. National Public Radio, 24 Mar 2020. www.npr.org/sections/coronavirus-live-updates/2020/03/24/820939536/fda-expedite-treatment-of-seriously-ill-covid-19-patients-with-experimental-plasma which contains the hyperlink: *emergency protocols approved by the FDA* which directs to: <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-applications-inds-cber-regulated-products/recommendations-investigational-covid-19-convalescent-plasma> (the February 11, 2021 which is the Wayback Machine first “captured”. ****Need to research this more as previous with the Wayback Machine pointed to April 8, 2020)

Reference 1 points to a URL that no longer exists and the other two in the body of the article points to the URL: <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-applications-inds-cber-regulated-products/recommendations-investigational-covid-19-convalescent-plasma> of February 11, 2021. Previously, if one copied to this URL into the Wayback Machine of the Internet Archive, the initial document in April 2020 which was an *ex post facto* document of April 8, 2020. This represents the now missing “reference “1” regarding justification for the criteria incorrectly attributed to the JAMA article of Wu Z, McGoonan JM...(see above)” of the FDA March 24, 2020 announcement. The Incorrect “Eligibility Criteria” criteria was the limiting factor regarding administration of CCP and Remdesivir until September 2, 2020 and August 28, 2020, respectively. The FDA was so “quiet” about these corrections that the VHA issued in November 2020 administration inclusion regarding Remdesivir which was (under the drug name VELKURY) as October 22, 2020 the only FDA fully-approved antiviral (NDA #214787) in the (early) treatment of COVID-19.

https://www.accessdata.fda.gov/drugsatfda_docs/apptletter/2020/214787Orig1s000ltr.pdf THE WRONG ADMINISTRATION INCLUSION CRITERIA remains the official criteria of the VHA listed on the internet to this day. https://vanf.app/CFU_PDF/Remdesivir_VEKLURY_November2020.pdf

[C. Andrus, 12-26-2024, Please note, this URL has been removed (eliminated/destroyed) from the Internet by the U.S. Department of Veterans Affairs and it was never captured by the Internet Archive. One can find copy of the document, at the following Internet URL sites that have been posted to the Internet Archive:

1. Andrus CH: BOOK 1 Dr Mr President... COVID 19 And Where We Went Wrong 2023 02 02. Published 2023-09-12, e92, <https://archive.org/details/book-1-dr-mr-president...-covid-19-and-where-we-went-wrong-2023-02-02/page/92/mode/2up>
2. Andrus CH: 04 BOOK 4 Biden Response to the Summary of Book 1 COVID 19 And Where We Went Wrong 2nd Attempt, Published 2024-03-05, e77 of e848, e93 of e848, e95 of e848, e218 of 382. E.g.: e377 of e848: <https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attempt/page/n76/mode/1up>

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY)	
Criteria for Use	
November 2020	
VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives	
<p>The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.</p> <p>The Product information should be consulted for detailed prescribing information.</p> <p>See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or http://vawww.pbm.va.gov for further information.</p>	
Exclusion Criteria	
If the answer to ANY item below is met, then the patient should NOT receive remdesivir	
<input type="checkbox"/>	Treated for COVID-19 as an outpatient
<input type="checkbox"/>	AST or ALT > 5 times the upper limit of normal
<input type="checkbox"/>	Hospitalized patients but NOT requiring supplemental oxygen*
<input type="checkbox"/>	Concomitant use of hydroxychloroquine or chloroquine
<input type="checkbox"/>	Current eGFR < 30 mL/min**
Inclusion Criteria	
The following must be fulfilled in order to meet criteria for remdesivir	
<input type="checkbox"/>	Hospitalized with SEVERE COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)***
Supplemental Information	
<p>Recommended initial duration of therapy is 5 days, with the potential to extend to 10 days in patients who are not improving or who remain critically ill. Therapy can be discontinued when the patient is appropriate for discharge, even if the full duration of therapy has not been given.</p> <p>*Use in hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe disease may be appropriate and should be adjudicated on a case by case basis</p> <p>**Patients with eGFR < 30 mL/min (or CrCl < 30-50 mL/min depending on the trial) were excluded from clinical trials and routine use is not recommended by the manufacturer. Use may be considered and adjudicated on a case by case basis if the benefit is felt to outweigh the risks, especially when renal function is likely to improve rapidly (e.g. dehydration). The mechanism of calculating renal function can be based on local guidance.</p> <p>***Remdesivir alone is not recommended alone for patients on mechanical ventilation or ECMO but may be considered in conjunction with corticosteroids in patients who have recently been intubated, according to the NIH Treatment Guidelines for COVID-19</p>	
<p>Prepared: November 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P</p> <p>Updated version may be found at PBM INTERNET or PBM INTRANET</p>	

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0.1 2022-09-11 Dear Mr. President Case Report EDIT 9-22-2022

2. **Mr. President, would you consider an Executive Order banning the present practice across the Executive Branch of the U.S. Government of “Overwriting” official documents without official designation of the document(s) rescinded?** You could then direct in the Executive Order the reinstatement of the practice that all official documents, policies, directives, and memos of all Departments of the Executive Branch of the U.S. Government document on the face sheet list the previously rescinded document, policy, directive, and/or memo on the present version that it was replacing.—that would be **TRUE GOVERNMENTAL TRANSPARENCY**. At present, if the replacement document is overwritten electronically and the exact URL is maintained, the replaced/rescinded document can **ONLY** be located, if the URL has not been changed, by pasting the existing URL into the “Wayback Machine” of the Internet Archive (300 Funston Avenue, San Francisco, CA, 94118, 415-561-6767). This can only occur if the Internet Archive is fortunate to have captured a digital version of the previously overwritten document!

End of: 5.0 2021-09-19: THE TRAGIC METHODOLOGY OF ELECTRONIC OVERWRITING OF OFFICIAL GOVERNMENT DOCUMENTS IS AN OBSTRUCTION OF JUSTICE

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December 2024

What follows is a more detailed discussion of electronic overwriting; concealing, changing, and removing URLs; and the lack of integrity displayed by our utilization of these paltering methodologies to be included as 0.9 Attachment VIII 08 076.0 2021-09-19 Tragedy of Electronic Overwriting of **Generalized Dismissal of Early Treatment with *Passive Immunization and Antivirals (Not Prophylaxis/Active Immunization)* in Persons Infected with COVID-19.** First and foremost, while the necessity and virtues of electronic overwriting are touted as a commonly utilized methodology with the justification of protecting information security¹, its common utilization throughout U.S. Government Documentation, Internet websites in general, and the Medical literature published electronically advances distortion and obscures, conceals, and destroys previously electronically posted information. Never in the literature is it discussed how electronic overwriting destroys the documentation or makes information essentially non-discoverable. For history, our thought processes or the documentation of the cognitive paths employed to conclusions, solutions, and policies have been muddled by overwriting to the point making unrecoverable previous documentation. It has become all too easy to obfuscate or destroy the short-comings of our progressive iterations of any specific document. The resultant overwritten iteration may thus demonstrate little adherence to our previous foundational tenets, promote lying as commonly accepted practice, and dismiss our integrity to paltering emphatic statements.

There is a multitude of policies throughout our society attempting to designate appropriate records handling. Unfortunately, as was stated over a century ago by James Cardinal Gibbons, an advisor to at least five U. S. Presidents: “Reform must come from within, not from without. You cannot legislate for virtue.” Yet, as individuals, groups and organizations, and as the Federal government, we champion the intent of doing right but, all too often, dismiss some, if not all correctness, subliminally codifying and proclaiming that which is wrong.

II. The rationale and methods of addressing Electronic Overwriting:

- A. Data bases and source material used in the preparation of this paper:
Attachment IV
- B. The analysis of public information obscured by electronic overwriting and URL changes **See that which follows in this Section II and subsequent Section III**
- C. Avoiding the misinformation of obfuscating, lies of omission, and paltering: In the development of this analysis, an extensive collection of source materials from Medical publications, Federal and International data bases, and other media were reviewed, correlated, and filed.(**Attachment III**) In dealing with

Federal documents of the VA, the NIH, the FDA, etc. fact checking of previous earlier versions of a document was many times difficult, if not impossible, if the URL of the previous or original document had been changed and/or the previous versions had been electronically overwritten. If the URL of the document was known and the **Internet Archive**⁸⁵⁻⁸⁶ had sometime in the last quarter of a century digitized the document, then using the **Wayback Machine**⁸⁷ (the search engine of the Internet Archive) and the present URL, previous captured versions of the document with the same URL could be located to scrutinize what had been electronically overwritten.

While there are many official policies and protocols positively detailing the methodology of electronic overwriting for secure data destruction^{AAAAAAA11-12-2024}, such an extensive electronic overwriting process destroys the previous unique-specifics of the documentation and terminates the paper-trail of document evolution. **This subliminal, ubiquitous methodology is utilized by many in the Executive Branch of the U.S. Government at the present time. In the preparation of this present analysis, electronic overwriting pervasively terminated the chronological history of a document's existence and was extremely detrimental to the development of this present analysis.** Within the Executive Branch of the Federal Government, this pervasive, overutilized, abusive *status quo* process of electronic overwriting destroys the document's paper-trail of the previous history which clearly violates the foundational intent of the Sarbanes-Oxley Act of 2002, 18 U.S.C. §1512(c)(1). Such electronic misdirection or outright destruction of information—I would allege—is a flagrant criminal violation of U.S. law as was confirmed recently in the opening sentence of *Fischer v. United States* by the Supreme Court of the United States on June 28, 2024:

The Sarbanes-Oxley Act of 2002 imposes criminal liability on anyone who corruptly “alters, destroys, mutilates, or conceals a record, document, or other object, or attempts to do so, with the intent to impair the object’s integrity or availability for use in an official proceeding.” 18 U.S.C. §1512(c)(1).

This pervasive process of electronic overwriting permeates the Executive Branch of the Federal Government at present time. In the VA’s Veterans Health Administration (VHA), there is a > 55-page document entitled Directive 6300 (1), RECORDS MANAGEMENT which specifically directs the process, organization, preservation, and archiving of all records in the VHA which is consistent with the National Archives directive: Universal Electronic Records Management (ERM) Requirements. No where is the word “overwriting” ever mentioned, permitted, or proscribed; but there are admonishments for maintaining documents, promoting access, and a prohibition against deletion of records and documentation:

What are the general recordkeeping requirements for agencies?

- (a) To ensure the adequate and proper documentation of agency programs, each program must develop recordkeeping requirements that identify:
 - (1) The record series and systems that must be created and maintained to document program policies, procedures, functions, activities, and transactions;
 - (2) The office responsible for maintaining the record copies of those series and systems, and the applicable system administrator responsible for ensuring authenticity, protection, and ready retrieval of electronic records;
 - (3) Related records series and systems;
 - (4) The relationship between paper and electronic files in the same series; and

- (5) Policies, procedures, and strategies for ensuring that records are retained long enough to meet programmatic, administrative, fiscal, legal, and historical needs as authorized in a NARA-approved disposition schedule.
- (b) Agencies must capture, manage, and preserve electronic records with appropriate metadata and must be able to access and retrieve electronic records, including electronic messages, through electronic searches.

36 CFR 1222.26

One blatant example of a violation of intent of 36 CFR 1222.26 within the VHA is the past eleven-year history of: VHA Directive 1063, UTILIZATION OF PHYSICIAN ASSISTANTS (PA), December 24, 2013. The initial URL document **declared the VHA preemptive over all State Medical Boards** base on the Constitution of the United States of America. Consistent with the fact that there does not exist any nationwide physician assistant (PA) licensing board (there are no nationwide physician nor national nursing licensing boards), all state medical boards credential all physician assistants (PAs) explicitly mandating that all PAs are working under a scope of practice of a licensed physician and are not independent practitioners which was controverted in the original version of VHA Directive 1063:

2. BACKGROUND: ...

c. Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts.

Today, when access is attempted employing the original URL of VHA Directive 1063 of December 24, 2013: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958, one is electronically diverted to a download on one's computer that is a .pdf file stamped AMENDED June 24, 2024: i.e., [file:///Users/andrusmd1/Downloads/1063\(2\)_D_2013-12-24%20\(21\).pdf](file:///Users/andrusmd1/Downloads/1063(2)_D_2013-12-24%20(21).pdf) thus preventing the access of the original version of VHA Directive 1063 of December 24, 2013.

On August 14, 2014, an electronic copy of VHA Directive 1063 was initially captured by the *Internet Archive* of the original version of December 24, 2013--8 months after VHA Directive 1063 was originally published (uploaded to the *Internet*):
https://web.archive.org/web/20140814150238/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

The May 17, 2022 version of VHA Directive 1063 which rescinded the misinterpretation / misapplication of the Supremacy Clause of the U.S. Constitution was captured by the *Internet Archive* on August 12, 2022, which was 3 months after the publication of the overwritten "AMENDED" VHA Directive 1063 of May 17, 2022 version and nine years and eight months from the publication of the original version of VHA Directive 1063):
https://web.archive.org/web/20220812082647/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

The latest version of June 18, 2024, was captured by the *Internet Archive* on July 18, 2024, which was one month after the publication in the June 18, 2024 version and eleven years and seven months from the publication of the original version of VHA Directive 1063 which contained the misinterpretation /misapplication of the Supremacy Clause of the U.S. Constitution.

https://web.archive.org/web/20240718213316/https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958

Besides perpetuating electronic overwriting of a previous misinterpretation/misapplication of a foundational statement of the U.S. Constitution, the adjustments to this document over the last 11 years are clear violations of the Sarbanes-Oxley Act of 2002 and also violate the VHA directives for amending and preserving the historical paper trail. Both “AMENDED” versions of May 17, 2022, and June 18, 2024, retained in all three versions of VHA Directive 1063 Transmittal Sheets the responsible, “signatory” party for all three versions of VHA Directive 1063 as listed: VHA Under Secretary for Health, Robert A. Petzel, M.D. Dr. Petzel resigned “under fire” over the Phoenix, Arizona VA scandal, in May 2014—six months after the original VHA Directive 1063 was signed officially by himself. Eight and ten years respectively, the “AMENDED” VHA Directives 1063 versions have covered-up the misinterpretation / misapplication (which violates States rights) of the Federal Government Supremacy Clause under the U.S. Constitution of the United States of America,

Please note, the VHA Under Secretary for Health, is the highest ranking Medical Officer in the U.S. Department of Veterans Affairs and leads the Veterans Health Administration (VHA). The VHA Under Secretary for Health oversees the 172 VA Medical Centers, >1300 CBOCs, and an annual budget of approximately \$325 billion. Dr. Petzel, along with the other four of us, Andrus, Bowen, Garthwaite, and Roswell, was interviewed for the VHA Under Secretary for Health on December 10, 1999, by the VHA USH Commission with three of the individuals: Drs. Garthwaite, Petzel, and Roswell being subsequently referred for vetting to *The White House* in early 2000. Although at that specific moment in history, Dr. Garthwaite’s name was submitted to the Senate and he was confirmed in the Spring of 2000, Garthwaite (2000 – 2002), Roswell (2002-2004), and Petzel (2010-2014) would serve as VHA Under Secretaries for Health.

Thus, using the *Internet Archive’s Wayback Machine* became the one most important fact-checking methodology employed extensively in the development of this paper providing a “following of the paper-trail” back to the origins of the documents regarding fundamental issues of the DHHS, the FDA, the NIH, the NIAID, the VHA, etc.

III. Fact checking and identifying misstatements, misinterpretations, and misrepresentations of official definitions result in *paltering* defilements, violations of Federal law, and lies of commission and omission (Attachments: III, IV, and V). As with electronic overwriting and URL obliteration, obfuscation of definitions is ethically wrong and led frequently to inappropriate or fallacious analyses, spurious conclusions, and incorrect policies and directives in U.S. Medicine’s addressing of the America’s COVID-19 epidemic. Ferreting out and defusing euphemisms became another keystone, focused methodology of this research:

The comedian George Carlin grounded his professional career in his satirizing our country’s fixation on euphemisms.²⁴⁷ In American society today, we seemingly have become unwittingly partners and victims to our willingness to euphemistically diminish our assessments to mediocrity--all too often, relegating the rejection of advancements of foundational concepts in Medicine to that of *Chronic Denial*. (Attachment VI)²⁴⁸⁻²⁵⁰ Throughout our society today, we have become comfortable with incorrectly expressing and flippantly misusing the definitions and meanings of words and phrases; ignoring essentials to the point of violating the intent of the rules of science, nature, and the laws of our country in our daily

lives; lying sometimes by commission but, most of the time, by omission and paltering; and championing *ad nauseam* the *ad hominem* attacks levelled against our fellow man as a standard methodology of bravado and self-assertiveness to discard the worth of our fellowman. During the COVID-19 epidemic, we, as individuals, in the United States of America through our institutions like that of Academic Medicine, Medical Publications, the U.S. Federal Government, etc. have distorted foundational concepts in Medicine which have resulted in disastrous outcomes for individuals, families, and communities throughout our country which were concomitant with >1,000,000 deaths associated with the American COVID-19 epidemic.

Much of our short-comings during the United States COVID-19 epidemic were ambiguous definitions, misinterpretation of definitions, and resultant obfuscations (***Palterings***) due to:

1. our naïve, pervasive utilization of euphemisms and manipulation of definitions
2. employment of electronic overwriting of policies, directives, and other documents with resultant subliminal electronic destruction of previous versions;
3. disregard for human rights by *de facto* suspension of EMTALA and desuetude of the Right to Try Act, etc.;
4. disregard for and misapplications of standardized definitions and policies of the FDA, the NIH, the CDC, the VA, and Medicine-in-general;
5. emphasis on our country's obsession that money can buy the right thing in Medicine which is far-from-the-truth;
6. disregard and daily misapplication to the truism that "...You cannot legislate for virtue"; and
7. unrestrained lies of commission and omission that indirectly resulted in greater than 1,000,000 deaths associated with these individuals' contraction of the coronavirus, SARS-CoV-2, (COVID-19).

Most importantly in the methodology of addressing of definition ambiguity, misinterpretation, misapplication, and paltering, the first part of the Results portion of this paper is a succinct outline: Table 1: Digital vs. Analog—Yes, No, Maybe in Medicine and Treatment of Covid-19. Table 1 is probably the most of important foundational methodology within this paper in the analyzing of branchpoint definitions with regards to the misapplications of definitions within Medicine, Medical Statistics, and the Legal Mandates involving specifically the U.S.A.'s response to the coronavirus, SARS-CoV-2, COVID-19. In **Table 1**, there is a categorizing of branchpoints as Positive, Relative, and Negative. In Medicine, as in life, there is only one absolute branch point: **Lived** versus **Died**. In our present computerized mindset of a "binary look" at the World today, we have mistakenly equated all decisions to Yes versus No equalling 1 versus 0, e.g.: Lived versus Died, etc. The World and Medicine overwhelmingly are of the Relative or Analog –not just Yes/No. **Table 1** is a hierarchical analysis that was then employed in the development of the **Results, Discussion, and Recommendations** portions of this paper. This analysis is based on the communications from April 5, 2020, going forward from Dr. Andrus to the National Institute for Allergy and Infectious Diseases (NIAID), Case file #12276; the FDA; the VA; *The White House*, etc. and the summary publication: Andrus CH: *Dear Mr. President: COVID-19 and Where We Went Wrong* of February 2, 2023, uploaded to the *Internet Archive* on 2023-

09-12 <https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02>

IV. Pathophysiology, Statistics, Legal Abridgments: Some of the aberrancies in our applications of foundational principles and tenets of Medicine and, I would allege, the violations of legal mandates throughout the last five years resulted from the repeated euphemistic manipulations of definitions, electronic overwriting, destruction-of-access-to-a-logical-pathway by changing electronically the ULS addresses, etc. Some of the analyses have been incorporated into the **Discussion** section of this paper and referenced to provide the reader the opportunity to explore these inconsistencies in more depth.

Unfortunately, all this information has been tainted with the euphemistic manipulation of definitions, the mistaken emphasis on self-serving theories, and the deemphasis of the clarity and importance of the pathophysiology of the disease cause by coronavirus, SARS-CoV-2, COVID-19. **The resultant logic of direct treatment (not prophylaxis) based on the clinical expression of the pathophysiology of COVID-19 with immunotherapy, antivirals, etc. has been dismissed for all intensive purposes.** Thus, the most important essence of this present paper's methodology is to provide the reader with reference foundational terminology and applications to organize pertinent facts from self-serving fiction. **Attachment III: Reductio ad Absurdum: The COVID-19 Tale of Two Presidents, the Ramifications of Fifty Years of American Scandal, Therapeutic Nihilism, and Medical Stupidity** is the face sheet of a 100-page document (between pages e31 to e130) summarizing that which was submitted to President Biden over the course of his term-in-office. The complete 848 page summary of submissions to the FDA, the NIAID, the VA, and *The White House* under NIAID case file #12276 was uploaded to the *Internet Archive* entitled: **Book 4: President Biden's July 7, 2023 Response Letter to Dr. Andrus' submission of 2023-04-27 update 11-7-23.pdf**:

Book 4: President Biden's July 7, 2023 Response Letter to Dr. Andrus' submission of 2023-04-27 update 11-7-23.pdf Internet Archive, Uploaded 2024 Feb 05, <https://archive.org/details/book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong/>, [Only 382 pages sometimes can be accessed, thus it was again uploaded on March 5, 2024, to the *Internet Archive* as Title: **0.4 Book 4 Biden response to the Summary of Book 1 COVID 19 And Where We Went Wrong 2nd Attempt** <https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attempt> *** NIH NIAID Case #12276

In the following Results section, the treatment with immunoglobulins of a viral infection with immunoglobulins and an outline of pertinent definitions in Table 1 are discussed. Then, using comparison statistics, e.g.: 2x2 contingency tables, a series of Chi Square analyses are correctly applied to contradict the invalid impression expressed throughout the literature regarding the efficacy of COVID-19 Convalescent Plasma and implemented by U.S. Medicine. 2x2 contingency tables of the FDA's published conclusions of August and September 2020 were reconstructed from the published FDA conclusions by a series of iterative Chi Square analyses using

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(3) **Level 3.** The staff practitioner is immediately available in the facility – campus for direct resident supervision according to local policy as approved by the Network Academic Affiliations Officer. The service chief is responsible for periodically reviewing cases done under Level 3 supervision to ensure that such supervision is appropriate.

Using the Wayback Machine another version of the Level 3 Supervision (now Level D) is identified: In VHA Handbook of July 27, 2005 signed by Jonathan B. Perlin, M.D. https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400_1hk_July_27_05.doc (Recission of the previous version of May 3, 2004 which cannot be found):

4. **Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.

Using the only other “hit” on the Wayback Machine of December 21, 2016, http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400_1hk_Oct2001.doc VHA 1400.1 has been removed completely and in its place is the website of the U.S. Department of Veterans Affairs which states: “Page Not Found.” **De facto, the U.S. DVA, VHA**

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Under the Supremacy Clause of the U.S. Constitution, States are prohibited from regulating or controlling the activities of the Federal Government without written Congressional consent; where Federal and State laws conflict, Federal law governs official actions of Federal employees. Examples of the types of activities that the Federal Government may establish are qualifications for employment and scopes of practice. Therefore, the establishment of scopes of practice for VA PAs defined by this Directive is without regard to State Practice Acts.

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40. Petzel RA: Utilization of Physician Assistants (PA), VHA Directive 1063 (1), Veterans Health Administration, U.S. Department of Veterans Affairs, December 24, 2013. https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 which is redirected when accessed to AMENDED June 24, 2024. Captured on July 22, 2023, by the *Internet Archive*. https://web.archive.org/web/20230722070741/https://www.va.gov/VHAPUBLICATIONS/ViewPublication.asp?pub_ID=2958 In **2. SUMMARY OF CHANGES** of the **Transmittal Sheet** which is still labelled **December 24, 2013** but in red has stamped: **AMENDED May 17, 2022** is: (1) Paragraphs 2.c. and 2.e. removes references to the Supremacy Clause reference and physician liability.—which means that the independent practice of a VHA Physician Assistant was rescinded returning all Physicians Assistants to the State Medical Board statutes outlining mandatory Physician scope of practice affiliations and legally mandated Physician oversight. The signatory official on this document is Robert A. Petzel, M.D., Under Secretary for Health who had been terminated over the Phoenix VAMC scandal 8 years prior to this as noted above in references 36 and 37.

41. Petzel RA: Utilization of Physician Assistants (PA) VHA Directive 1063(2), December 24, 2013 **AMENDED June 24, 2024**. When one uses a search engine like GOOGLE or enters the official URL of this document site: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2958 , one is electronically shifted to a .pdf file, e.g.: [file:///Users/andrusmd1/Downloads/1063\(2\)_D_2013-12-24%20\(6\).pdf](file:///Users/andrusmd1/Downloads/1063(2)_D_2013-12-24%20(6).pdf). The <https://...> URL version was captured by the *Internet Archive* on July 18, 2024. The signatory official on this document is still Robert A. Petzel, M.D., Under Secretary for Health, who had been terminated over the Phoenix VAMC scandal 10 years prior to this as noted above in references 36 and 37. https://web.archive.org/web/20240718212213/https://www.va.gov/VHApublishations/ViewPublication.asp?pub_ID=2958

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After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired Fighting for Care narrated by Diane Sawyer. 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212>) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Temple, TX VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, *ABC News PrimeTime Live*, for "Fighting for Care," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents— I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Temple TX VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

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Antibodies have been used for a century for the prevention and treatment of infectious diseases (Table 1). In bacterial disease, antibodies neutralize toxins, facilitate opsonization, and, with complement, promote bacteriolysis; in viral disease, antibodies block viral entry into uninfected cells, promote antibody-directed cell-mediated cytotoxicity by natural killer cells, and neutralize virus alone or with the participation of complement.

Prior to the use of antibiotics, antibodies were the only specific agents for the treatment of certain infections. Although this role has largely been supplanted by antibiotics, there still remains a crucial role for antibody in the treatment of certain infectious diseases (Table 1). Since several excellent reviews are available, this article will emphasize new developments (30, 31, 101, 164, 165).

Antibodies can be administered as human or animal plasma or serum, as pooled human immunoglobulin for intravenous (IVIG) or intramuscular (IG) use, as high-titer human IVIG or IG from immunized or convalescing donors, and as monoclonal antibodies (Mab) (30, 164, 178). The therapeutic use of Mab is increasing dramatically, but only one (palivizumab for respiratory syncytial virus [RSV]) has been licensed for prophylaxis of an infectious disease.

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Footnote at bottom of every page of this Annotated Bibliographic Timeline:

----- May 30, 2022 -----
 This is a COVID-19 Timeline Bibliography for Educational Purposes ONLY in the presentation of this information before the people of the United States³ of America (U.S.A.), the World, and specifically the President of the U.S.A. without any compensation to the author. All submissions including this timeline bibliography can be obtained under the Freedom of Information Act (FOIA) by formally requesting a copy of NIAID Case #12276 from the FIOA Officer of the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health, Bethesda, Maryland

Treatment: *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

Prevention: *Active Immunization:* Vaccines

This submission is NOT for financial gain but for educational purposes only for ALL the American people

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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– Table 1 is a composite of Tables to explain definitions grouped in the following themes:

General Pertinent Definitions

Medicine and Infectious Diseases in general and COVID-19 in specifics

Epidemiology

Pathophysiology

Immunology

Treatment

Prophylaxis

Statistics and Medical Research

Legislative and Legal Issues

General Pertinent Definitions

Lived		Died	
Success ¹⁻³	Unsuccessful in part	Failure	
Digital (1) ⁴	Analog	Digital (0)	
Yin or Yang ⁵	Yin and Yang	Yin or Yang	James JJ: COVID-19: Yin and Yang and Herd Immunity is an outstanding analysis of the U.S. response to COVID-19
Truth ^{15,48-52,64-79}	Euphemisms ¹⁵ Paltering ⁵⁰⁻⁵¹	Lying, commission or omission ⁴⁸⁻⁴⁹	

Medicine and Infectious Diseases in general and COVID-19 in specifics

Not Infected ⁶	Infected but asymptomatic	Symptomatic	
Cured ^{7,8}	Treated		
	Humoral vs cellular immunity and Treatment vs. Prophylaxis ⁹		
Short-term outcome ¹⁰	Short-term outcome	Short-term outcome	
Long-term outcome	Long-term outcome	Long-term outcome	
Primary Endpoints ¹¹⁻¹²	Secondary Endpoints		
	Synergism vs monotherapy (the Magic Bullet) ¹³⁻¹⁵ Antiviral therapy vs immunotherapy in COVID-19 ¹⁶		

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Epidemiology

Pandemic versus Epidemic ¹⁷⁻¹⁹	Endemic		
N95 Mask ²⁰⁻	Prevents 95% of passage of ≥ 300 nm	Permits 5% passage of ≥ 300 nm	
SARA-CoV-2 ~0.1 μ m in diameter 100 nm (but the virus usually attached to a droplet)			
Respiratory droplets >5 – 10 μ m in diameter 5000 nm – 10,000 nm			
Sputum droplets range 0.05 μ m to 500 μ m or 50 nm to 5 x 10 ⁵ nm			
Sub-micron droplets (0.02 -0.3 μ m) 20nm to 300 nm			
	Herd Immunity	Less than herd immunity	

Pathophysiology

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Immunology

Humoral and Cell Immunity

Endogenous v Exogenous

Active Immunization

Administration of exogenous specific antigens (Ag) by vaccination to produce endogenous antibodies (Abs) in the individual against those specific antigens (Ag). Normally, what is thought of as a vaccination, is a stimulation within the individual of B-cell development to produce endogenous antibodies (e.g: IgM, IgG, IgA) to specific Ags presented to the individual being vaccinated. In the individual, development of IgG against some Ag of the COVID-19 requires roughly two weeks for full effective immunologic response. With the time delay of the development of adequate amounts of endogenous IgG in the COVID-19 individual over two weeks, vaccination (Active Immunization) is *prophylaxis* not *treatment* of actively, acutely infected individuals as the most effectiveness time of IgG viral replication suppression is during the viremic phase of COVID-19 and not later during the time of cytokine cascade and bradykinin storm. Active immunization by systemic vaccines long-term acts through a complex cellular/humoral mechanism to address systemically the viremia early in the course of the disease (72-96 hours). In the case of respiratory viruses, nasal resistance to the SARS-CoV-2 virus is not protective due to systemic immunoglobins previously resultant from vaccination or previous systemic infection but is dependent on mucosal IgA, which requires only ~5 days after COVID-19 nasal exposure to reach adequate levels. This IgA protection is limited in proximity to the nares mucosa and has a short half-life long-term thus being ineffective for subsequent exposures without nasal reinoculation.

Passive Immunization

Administration of exogenous antibodies to provide immediate systemic immunologic response (IgG). Application of passive immunization is *treatment* not *prophylaxis* when administered (within 72-96 hours of diagnosis) to an newly infected individual. (Passive immunization can be used as a prophylactic agent but administrations should be renewed every 8 weeks the concentration of exogenous antibodies diminish by ½ life decay. A naturally occurring form of Passive Immunization is the passage of maternal Abs across the placenta to the fetus). Passive immunization when given early has been the mainstay for the treatment of infections for over a century especially when pharmacologic antivirals are not available; and when antiviral pharmacologic agents are available, passive immunization can be used successfully synergistically. Convalescent plasma and sera, polyclonal antibodies, and monoclonal antibodies; γ -globulin, IVIG, etc.; and other specific plasmas and sera (Pasteur's rabies vaccine, hypertet, RhoGam, etc.) are all, variations of Passive immunization)

Magic Bullet only

Synergism

Non-treatment

Treatment versus Prophylaxis

Nihilism

Biosimilar

Non-Biosimilar

FFP v CCP

Monoclonal antibodies vs. Polyclonal Antibodies

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
<i>GlaxoSmithKline's Sotrovimab</i>			
<i>Eli Lilly's Bebtelovimab</i>			
Given in < 72 hours from diagnosis		Given in >72 hours from diagnosis	
Given in adequate titer doses		Given in inadequate titer doses	
Two monoclonal antibody cocktails			
<i>Eli's Bamlanivimab plus Etesevimab</i>			
<i>Regeneron's Casirivimab plus Imdevimab</i>			
Given in < 72 hours from diagnosis		Given in >72 hours from diagnosis	
Given in adequate titer doses		Given in inadequate titer doses	
Polyclonal COVID-19 Convalescent Plasma (CCP) and Serum			
Given in < 72 hours from diagnosis		Given in >72 hours from diagnosis	
Given in adequate / high titer doses		Given in inadequate titer doses	
Given several times for a cumulative high dose titer		Given once with low dose titer	
for a cumulative high dose titer			
Adverse reactions and ADE			

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
<u>Treatment:</u>			

Prophylaxis:

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
<u>Statistics and Medical Research</u>			

$H_0 < 0.95$, sustained

$H_0 > 0.95$, rejected

$H_0 > 0.95$, rejected

$H_0 < 0.95$, sustained

Powered, appropriate study size

Unpowered, inadequate study size

Confidence levels

> 0.95, 2 S.D. from the mean

> 0.99, 3 S.D. from the mean

< 0.99 SD from mean but > 0.95 SD from mean

< 0.95, less than 2 S.D. from the mean

< 0.99, less than 3 S.D. from the mean

Screening test, > 0.95

Pap smear

Pregnancy test

Qualified screening test

Not a screening test, < 0.95

Cologuard with qualitative restriction
“those at normal risk”

Cologuard

- a. Independent variables Dependent variables
 - i. Time
 - ii. Age
 - iii. Direct initiation of treatment e.g: drug, biologic, operation, physical manipulation, or mechanical treatment
- b. Dependent variables
 - i. Life and Death
 - ii. Decrease in symptomatology, decrease in severity of illness, and “Cure”
 - iii. First and Second Order Kinetics
- c. Evidence Based Medicine
 - i. RCT
 - ii. AACT
 - iii. Others
- d. Outcomes/Results
 - i. End-points
 - ii. Exclusion v Inclusion
 - iii.
- e. FDA
- f. NIH

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
g. NIAID			
h. Safety versus Efficacy – Phase I, II, III studies			
i. Expanded Access = Compassionate Use			
j. Approved versus Authorized			
k. EUA			
l. Evidence Based Medicine			
m. Randomized Controlled Studies			
n. Endpoints			
o. “Revoked”			
	i. Medical Statistical definitions, postulates, and applications:		In clinical and research medicine, seldom is there a comparative situation in which differences within a complete population can be measured and ascertained to be significant. In the simplest terms, medical statistics is a methodology of ascertaining (1) if a studied group is (“statistically”—which is redundant terminology) significantly different from a control group within the parameters of adequate sampling, (2) that the studied and controlled groups adequately represent the population, and, most of all, (3) the analyses avoid inherent bias. Seven decades ago, the best selling book: <i>How to Lie with Statistics</i> by Darrell Huff poked fun at our inherent inabilities to naïvely accept that which is not provable and, all too often, not true but are marketed as erroneous truths through our present day media, politics, publications, textbooks, etc. For decades in American media, one of the most “familiar” classic marketing examples that has no significance statistically but is touted seemingly as a truism was:
	ii. 4 out of 5 dentists recommend sugarless gum for those that chew gum!		
	iii. While the mantra today is to strive for <i>Evidence Based Medicine</i> , the vast majority of medical studies published during the American COVID-19 epidemic were flawed as they had subliminal errors in statistical application and reasoning, incorrectly defined and applied nebulous endpoints, and, all too often, amplified statistical power and significance where there was none. All too often, today, the eagerness to confirm questionable theories, impatience to advance one’s personal assertions, and the race to quickly proclaim and publish have clouded that which is truly provable. Robert Condon, M.D., F.A.C.S. wrote about these foibles a half a century ago in an editorial entitled, <i>Type III Error</i> :		
	1. Type I and type II errors are the two classic pitfalls in statistical analysis: finding a difference when there is none (type I) and failure to find a true difference (type II). There is, in addition, another important error that regularly appears in scientific journals. This error, <i>the type III error</i> , occurs whenever the conclusions drawn are not supported by the data present....		

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
	<p>iv. By defined medical standards, the null hypothesis (H_0) in the simplest terms means that when one compares two groups, A and B, then $A = B$. One can only reject the null hypothesis --thus stating that $A \neq B$ implying a statistical significance, if the comparison falls outside of a predesignated confidence level.</p> <p>v. While statistical boundaries are difficult to universally define, a segment of <i>Hypothesis Testing, P values, Confidence Intervals, and Significance</i> by Jacob Shreffler and Martin R. Huecker, NCBI Bookshelf, a service of the National Library of Medicine, provide a succinct synopsis for clinical and research Medicine:</p> <ol style="list-style-type: none"> Significance Significance is a term to describe the substantive importance of medical research. Statistical significance is the likelihood of results due to chance.[3] Healthcare providers should always delineate statistical significance from clinical significance, a common error when reviewing biomedical research.[4]. When conceptualizing findings reported as either significant or not significant, healthcare providers should not simply accept researchers' results or conclusions without considering the clinical significance. Healthcare professionals should consider the clinical importance of findings and understand both p values and confidence intervals so they do not have to rely on the researchers to determine the level of significance.[5]. One criterion often used to determine statistical significance is the utilization of p values. P Values P values are used in research to determine whether the sample estimate is significantly different from a hypothesized value. The p-value is the probability that the observed effect within the study would have occurred by chance if, in reality, there was no true effect. Conventionally, data yielding a $p < 0.05$ or $p < 0.01$ is considered statistically significant. While some have debated that the 0.05 level should be lowered, it is still universally practiced[6]. ... While researchers have historically used p values, experts who find p values problematic encourage the use of confidence intervals.[8]. P-values alone do not allow us to understand the size or the extent of the differences or associations.[3]. In March 2016, the American Statistical Association (ASA) released a statement on p values, noting that scientific decision-making and conclusions should not be based on a fixed p-value threshold (e.g., 0.05). They recommend focusing on the significance of results in the context of study design, quality of measurements, and validity of data. Ultimately, the ASA statement noted that in isolation, a p-value does not provide strong evidence.[9] ... Confidence Intervals (CI) A confidence interval provides a range of values with give confidence (e.g., 95%), including the accurate value of the statistical constraint within a targeted population.[12]. Most research uses a 95% CI, but investigators can set any level (e.g., 90% CI, CI, 99% CI).[13]. A CI of 95% provides a range with the lower bound and upper bound limits of a difference or association that would be plausible for a population.[14]. Therefore, a CI of 95% CI, indicates that if a study were to be carried out 100 times, the range would 		

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
contain the true value in 95,[15] confidence intervals provide more evidence regarding the precision of an estimate compared to p-values.[6]			

vi. In its simplest form, for the clinical application of a medical study in the development of the “p value”, the confidence interval, etc. in comparison 2x2 statistics, is expressed as **Sensitivity** and **Specificity**:

1. Sensitivity =
i.
$$\frac{\text{(True positive)}}{\text{(True positive + False negative)}} \times 100$$

2. Specificity =
i.
$$\frac{\text{(True negative)}}{\text{(True negative + False positive)}} \times 100$$

vii. In the **DISCUSSION** that follows, the wholesale misapplication to these statistical concepts have amplified an uncertainty, confusion, and distrust towards American Medicine of the American people and throughout the world during our nation’s disordered addressing of COVID-19. Other of statistical concepts that are important in one’s assessment of the premise of this paper can be found in the following:

- 1. Independent variables versus dependent variables
- 2. Mean, Median, and Mode
- 3. Skewness
- 4. Exclusion versus Inclusion
- 5. Endpoints
- 6. Negative Results and their interpretations
- 7. Equilibrium
- 8. 1st order kinetics and Zero order kinetics
- 9. Half-life

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Medical Research

Clinical trials			
Phase 1 Trial			
Safety		Unsafe	
Phase 2 & 3 Trials			
Efficacy		No sign of benefit	

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Legislative and Legal Issues

EMTALA			
Application of patient rights: diagnosis, treatment, disposition		Non-application of EMTALA (Suspension of EMTALA, March 13, 2020)	
Right to Try Act of 2018, PL-115-176			Never implemented during COVID-19 epidemic
Implementation (Never invoked officially during COVID-19 except <i>de facto</i> for Trump, Giuliani, Christi, and Carson)			
Preservation of Documentation		Destruction of Documentation	
Overwriting for security reasons		Overwriting to change documentation Removing URLs	

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Biosimilar, FDA COVID-19 Convalescent Plasma Guidance for Industry, and Fresh Frozen Plasma numbers

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Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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FDA COVID-19 Convalescent Plasma Guidance for industry

36. 2/24/2020 Wu Z, McGoogan JM: Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) Outbreak in China: Summary of a report of 72314 cases from the Chinese Center for Disease Control and Prevention. JAMA. Published online February 24, 2020. Doi:10:1001/jama.2020.2648. <https://jamanetwork.com/journals/jama/fullarticle/2762130>
37. 3/24/2020 Investigational COVID-19 Convalescent Plasma – Emergency INDs. https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf or https://natap.org/2020/COVID/032320_39.htm
 FDA: Investigational COVID-19 Convalescent Plasma – Emergency INDs. “A licensed physician must request the Emergency IND (eIND) and obtain the COVID-19 convalescent plasma from a blood center. FDA does **not** provide COVID-19 convalescent plasma for eINDs. Investigational COVID-19 Convalescent Plasma – Emergency INDs Frequently Asked Questions (/media/136470/download).

U.S. Food and Drug Administration: Investigational COVID-19 Convalescent Plasma – Emergency INDs, March 24, 2020. https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
<ul style="list-style-type: none"> • Eligible patients for use under expanded access provisions: <ul style="list-style-type: none"> ◦ Must have laboratory confirmed COVID-19 ◦ Must have severe or immediately life-threatening COVID-19, for example:¹ <ul style="list-style-type: none"> ▪ Severe disease is defined as: <ul style="list-style-type: none"> ▪ dyspnea, ▪ respiratory frequency ≥ 30/min, ▪ blood oxygen saturation $\leq 93\%$, ▪ partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300, and/or ▪ lung infiltrates $> 50\%$ within 24 to 48 hours ▪ Life-threatening disease is defined as: <ul style="list-style-type: none"> ▪ respiratory failure, ▪ septic shock, and/or 			
<p>https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convale... 2/3</p> <hr/> <p>27/3/2020 Investigational COVID-19 Convalescent Plasma - Emergency INDs FDA</p> <ul style="list-style-type: none"> ▪ multiple organ dysfunction or failure 			
<ul style="list-style-type: none"> ◦ Must provide informed consent <p>¹Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. <i>JAMA</i>. Published online February 24, 2020. doi:10.1001/jama.2020.2648</p>			

NO WHERE in the aforementioned reference #1 by *Wu* and *McGoogan* upon which officially the U.S. FDA based the *Eligibility Criteria* for administration of COVID-19 Convalescent Plasma from March 24, 2020 to September 2, 2020 is “CONVALESCENT”, “PLASMA”, “ELIGIBILITY” or “CRITERIA” mentioned even once !!!!

2020-03-24 Investigational COVID-19 Convalescent Plasma – Emergency INDs. (This is the NATAP Verbatim internet copy of reference 28 in its entirety that I have copied and pasted verbatim to follow from https://natap.org/2020/COVID/032320_39.htm as this is an original copy I can find on the Internet which is of the FDA’s directive of March 24, 2020 that directed all the *misdirection based on only one reference #1 by Zunyou Wu, M.D., PhD, Jennifer M. McGoogan, PhD which never mentions COVID-19 Convalescent Plasma nor recommends* the eligibility criteria justifying the FDA authorizations of COVID-19 Convalescent Plasma (CCP), and EUAs that were to follow in the next 10 months.)

PLEASE NOTE THAT WEB SITE REFERENCED JUST BELOW MARCH 24, 2020 <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-ind> IS A HYPERLINK THAT BECAUSE OF THE FDA

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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OVERWRITING PRACTICES AS PERMITTED BY THAT WHICH WAS PUBLISHED IN THE FEDERAL REGISTER on March 25, 2020 now points *ex post facto* to the future FDA website: Recommendations for Investigational COVID-19 Convalescent Plasma, February 11, 2021, and then with each overwrite *ad infinitum*. (One can trace back the referenced website with modifications using the *Internet Archive (Wayback Machine* -- <https://archive.org/web/>) to April 8, 2020. The FDA version of the verbatim document below must have been referenced between March 24, 2020 to ~April 8, 2020 was electronically replaced so that media articles (listed below) referencing the March 24, 2020 announcement *ex post facto* references to April 8, 2020.

*I, therefore, allege that there was **Blatant Misdirection** of the official FDA documentation of March 24, 2020 in which the **Eligibility Criteria** is wrongly attributed to reference #1 which initiated the administration of CCP TO ONLY EXTREMELY ILL INDIVIDUAL PATIENTS AT THE **WRONG TIME** (not during the early viremic phase or prophylactically) which was probably a **Federal Criminal Offense** by someone in the FDA, Department of Health and Human Services, and/or The White House.*

I allege, on behalf of the American people, this **misdirection of official federal FDA** documentation facilitated: 1) misdirected CCP application at an inappropriate (wrong) **late-in-time** in the course of the disease in >700,000 individuals having contracted COVID-19 and having developed life-threatening systemic complications (e.g., bilateral pneumonitis, kidney failure, etc.; 2) promoted nonsensical, inappropriate medical research/NIH ClinicalTrials (<https://www.clinicaltrials.gov/> of CCP at the wrong administration time); 3) promoted violation of PL-115-176--*The Right to Try Law*--by promoting NON Completion of Phase I Studies; 4) promoted CCP application late in the individual's COVID-19 disease (which is the **WRONG TIME** to administer *Passive Immunization*); 5) led to the *de facto* discrediting of *Passive Immunization* as a **treatment**; 6) promoted *de facto* physician abandonment of their individual COVID-19 positive patients early in the course of the individual's disease (viremic phase); and 7) inadvertently led to greater than a half-of-a-million American deaths!

Below, copied and pasted *verbatim* from the National AIDS Treatment Advocacy Project (NATAP) https://natap.org/2020/COVID/032320_39.htm is the **original** NATAP copy found of the FDA's directive of March 24, 2020 that directed the **misdirection** regarding the eligibility criteria, FDA authorizations of COVID-19 Convalescent Plasma (CCP), and EUAs that were to follow for the next 10 months.

Investigational COVID-19 Convalescent Plasma - Emergency INDs

38. 3/25/2020 Regional Platform on Access and Innovation for Health Technologies^{PRAIS}, Pan American Health Organization, World Health Organization: FDA: Investigational COVID-19 Convalescent Plasma – Emergency Investigational New Drug Applications, March 25, 2020. <https://prais.paho.org/en/fda-investigational-covid-19-convalescent-plasma-emergency-investigational-new-drug-applications/>

4/3/2020 Investigational COVID-19 Convalescent Plasma – Emergency INDs (could no longer be found on the Internet—therefore have scanned this document of April 3, 2020 with my response letters to Dr. Fauci and Hahn and the President with USPS documentation of mailing into pdf file: 04 Scan of 4_3_20 Investigational CCP FDA Emerg INDs.pdf)

39. 3/26/2020 Hopkins Tanne J: Covid-19: FDA approves use of convalescent plasma to treat critically ill patients. BMJ 2020; 368:m1256 doi: 10.1136/bmj.m1256 (Published 26 March 2020). <https://www.bmj.com/content/bmj/368/bmj.m1256.full.pdf>

Dear Mr. President: I apologize for copying and pasting the following excerpted as this is copyright protected material by the BMJ Publishing Group Limited but I am presenting this to you as **Educational Material** BUT the URL to which the references point were changed

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
by the FDA so that the eligible criteria justifying reference “1” of March 24, 2020 is extremely difficult to find: Wu Z, McGoogan JM. Characteristics of and Important Lessons from the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72,314 Cases from the Chinese Center for Disease Control and Prevention. JAMA. Published online February 24, 2020. –C. Andrus, M.D.			
Plasma from people who have recovered from covid-19 may contain antibodies to the virus that causes the disease and might be effective against the infection, the FDA said. Convalescent plasma has been studied in outbreaks of other respiratory infections, such as H1N1 influenza, SARS, and MERS. “Although promising, convalescent plasma has not been shown to be effective in every disease studied” and therefore clinical trials were needed to see if it was useful in covid-19, the FDA cautioned.			
The FDA told doctors wanting to study the use of convalescent plasma to follow the usual system for an investigational new drug (IND) application.			
The plasma must be collected from recovered patients who can donate blood, have had no symptoms for 14 days, and have had negative results on covid-19 tests.			
However, given the current public health emergency, the FDA said it was providing emergency access to convalescent plasma for patients “with serious or immediately life threatening covid-19 infections.”			
Severe disease is defined as dyspnoea, respiratory frequency ≥ 30 breaths per minute, blood oxygen saturation $\leq 93\%$, ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO ₂ /FiO ₂) 50% within 24 to 48 hours.			
Life threatening disease is defined as respiratory failure, septic shock, or multiple organ dysfunction or failure. In such cases, doctors can submit a form online or call FDA’s hotline telephone number (1-866-300-4374) to get verbal approval for treatment, which is promised within four to eight hours.			
Jeffrey Henderson of Washington University School of Medicine in St Louis, Missouri, told National Public Radio, “The FDA just opened the floodgates. Our institution is scrambling to be ready to use this. There are many others, I’m sure.” ³			
1 FDA. Investigational covid-19 convalescent plasma—emergency INDs. https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ideprocess-cber/investigational-covid-19-convalescent-plasma-emergency-inds			
2 Hixenbaugh M. FDA will allow doctors to treat critically ill coronavirus patients with blood from survivors. NBC News 2020 Mar 24. www.nbcnews.com/news/us-news/fda-will-allowdoctors-treat-critically-ill-coronavirus-patients-blood-n1167831			
3 Palca J. FDA expedites treatment of seriously ill covid-19 patients with experimental plasma. National Public Radio, 24 Mar 2020. www.npr.org/sections/coronavirus-liveupdates/2020/03/24/820939536/fda-expedite-treatment-of-seriously-ill-covid-19-patientwith-experimental-plasma			
Published by the BMJ Publishing Group Limited. For permission to use (where not already granted under a licence) please go to http://group.bmj.com/group/rights-licensing/permissions			
40. Joyner M:			
41. 4/4/2020 Joyner M, (Principal Investigator): COVID-19 expanded access program—Convalescent Plasma COVID-19 (coronavirus) Treatment—Mayo Clinic. This is the first date of the preservation of the website by the <i>Internet Archive</i> (Wayback Machine). Origin of the FDA/Mayo Clinic expanded access program. (An expanded access program is for “compassionate use” only—and thus cannot be used as a Randomized Controlled Trial by the definitions of the NIH and the FDA) https://web.archive.org/web/20200404010134/https://www.uscovidplasma.org/			

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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The protocol requires the patient or family member to consent to receiving plasma from someone who has recovered from COVID-19. Their plasma has substances that could improve chances of recovery. Only hospitalized patients referred by their health care provider will participate in this protocol.

Hospitalized patients are eligible to receive convalescent plasma if:

- They are 18+ years of age
- They have laboratory-confirmed diagnosis of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19
- They are admitted to an acute care facility for the treatment of COVID-19 complications
- They have severe or life-threatening COVID-19, or judged by the treating provider to be at high risk of progression to severe or life-threatening disease
- There is informed consent provided by the patient or healthcare proxy

Severe COVID-19 is defined by one or more of the following:

- Shortness of breath (dyspnea)
- Respiratory frequency $\geq 30/\text{min}$
- Blood oxygen saturation $\leq 93\%$
- Partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300
- Lung infiltrates $> 50\%$ within 24 to 48 hours

Life-threatening COVID-19 is defined as one or more of the following:

- Respiratory failure
- Septic shock
- Multiple organ dysfunction or failure

Michael J. Joyner, M.D., Summary, Mayo Clinic. <https://www.mayo.edu/research/faculty/joyner-michael-j-m-d/bio-00078027>

42. 4/7/2020 Rivera N: Medical Task Force COVID-19 (Puerto Rico): Investigational COVID-19 Convalescent Plasma Emergency Investigational New Drug, Date April 7, 2020. <https://covid19tf.rcm.upr.edu/wp-content/uploads/sites/45/2020/04/Protocolo28-Convalescent-Plasma-1.pdf>

Since only limited data exists at this moment regarding the effectiveness of this therapy, it cannot be routinely recommended or used as a proven treatment option. The Food and Drug Administration (FDA) has provided several pathways to administer or study the use of convalescent plasma in COVID-19 patients:

- Clinical Trials: Investigators wishing to study the use of convalescent plasma need to submit a request to FDA for investigational use under the traditional IND regulatory pathway (21 CFR 312).

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
	<ul style="list-style-type: none"> Expanded Access: FDA is working with multiple federal partners and academia to open an expanded access protocol to facilitate access to COVID-19 convalescent plasma. For patients with, or at risk of, severe or life-threatening COVID-19 disease who are not eligible or who are unable to participate in randomized clinical trials, access may be available through participation of acute care facilities in an investigational expanded access protocol under an IND already in place. Single Patient Emergency IND: For patients who are not able to participate in a clinical trial or in an expanded access program, given the public health emergency FDA also is facilitating access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of the patient's physician requesting a single patient emergency Investigational New Drug Application (eINDs) for the individual patient under 21 CFR 312.310. This process allows the use of an investigational drug for the treatment of an individual patient by a licensed physician upon FDA authorization. This eIND process is not for the use of COVID-19 convalescent plasma for the prevention of infection. 		

43. 4/8/2020 FDA: Recommendations for Investigational COVID-19 Convalescent Plasma.
<https://web.archive.org/web/20200408215026/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma> which hyperlinked on 4/8/2020 to that which follows on 4/14/2020:
44. 4/14/2020 FDA first document of Guidance for industry:
<https://web.archive.org/web/20200414181056/https://www.fda.gov/media/136798/download>
45. 4/17/2020 Langi DM, Jr., De Santis GC, Bordin JO: Covid-19 convalescent plasma transfusion. Hematol Transfus Cell Ther. 2020 Apr-Jun; 42(2): 113 – 115. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7164882/pdf/main.pdf>

... Therefore, all therapeutic options for the potentially lethal COVID-19 infection must be discussed ethically and scientifically. Historically, convalescent plasma (CP), a passive immunotherapy, has been used as a possible therapeutic option when no proven specific vaccine or drug is available for emerging infections.^{1,2} The administration of convalescent plasma or immunoglobulins has been shown to shorten the hospital stay and reduce the mortality rate in patients with SARS who did not respond to methylprednisolone in uncontrolled non-randomized clinical trials.^{3,4} Cheng et al. investigated 1775 SARS patients and found that 80 patients transfused with SARS convalescent plasma had a lower mortality rate, compared to non-transfused patients (12.5% vs. 17%).⁴

Conclusions:

Analogous to the SARS, the COVID-19 infection progresses with an intense inflammatory response that eventually causes serious lung damage, increasing the mortality risk. In the absence of a definitive curative management, many treatment algorithms have been explored in the treatment of the COVID19. Among possible interventions, the use of plasma collected from recovered patients shows an initial promise, however published results of rigorous clinical trials are needed before we may draw definitive effectiveness conclusions on this passive antibody therapy.

The administration of the COVID-19 convalescent plasma must, however, fulfill some requirements related to availability of COVID-19 recovered donors: well-designed study protocols to guarantee the efficacy analysis of such an intervention; governmental and institutional compliance, and; laboratory support to perform serological and molecular assays, including the measurement of viral neutralization and immune response.¹¹ In addition, the connection between hospitals, blood centers and the plasma industry must follow flawless strategies, as plasma units may be frozen before distribution or be manufactured as concentrated COVID-19 immunoglobulin.

46. 5/1/2020 Pérez C, Marín-Lahoz J: Serosurveys and convalescent plasma in COVID-19. EClinicalMedicine 23 (2020) 100370.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7252163/pdf/main.pdf>

The current pandemic is not only overwhelming the health systems of the affected countries but also is killing thousands of other ways healthy adults. Convalescent plasma has been proposed [1] and approved to treat COVID-19 based on the experience acquired treating other viral diseases such as influenza, Ebola, and SARS [2]. It is considered a safe treatment (at least its side effects and contraindications are well known) and it has proven to be efficacious in several viral infections for more than a century. Currently, several countries and health institutions are trying to gather convalescent sera for either empirical treatment or clinical trials. Based on the WHO interim guidance developed for the 2014 Ebola outbreak [3], convalescent plasma has advantages over other proposed treatment: it requires low technology (and therefore it can be produced where required independent of pharmaceutical companies), it is low cost and its production is easily scalable as long as there are sufficient donors.

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
47. 5/26/2020	FDA update 5/1/2020: https://web.archive.org/web/20200526150255/https://www.fda.gov/media/136798/download		
48. 5/30/2020	Alsuliman T, Alasadi L, Alkharat B, Srouf M, Alrstom A: A review of potential treatments to date in COVID-19 patients according to the stage of the disease. Current Research in Translational Medicine 68 (2020) 93 – 104. https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC7260520&blobtype=pdf		
	Convalescent plasma The FDA has recently approved convalescent plasma for serious or immediately life-threatening COVID-19 infections under emergency Investigational New Drug Application (eINDs) [80]. Convalescent plasma has been previously studied during other epidemics including H1N1 influenza virus pandemic, SARS-CoV-1 epidemic, and the MERS-CoV epidemic. Recently, a preliminary case series of five intubated COVID-19 patients with ARDS showed promising results. These patients received 400 ml of convalescent plasma containing neutralizing SARS-CoV-2-specific antibody (IgG) from recovered COVID-19 donors. All patients had gradual clinical and radiological improvement within 3 days and four patients no longer required respiratory support by day 9, viral loads also became negative within 12 days after transfusion. Seven clinical trials are currently registered [7,38,81].		
49. 7/17/2020	Wortham JM, Lee JT, Althomsons S, Latash J, Davidson A, Guerra K, Murray K, <i>et.al.</i> : Characteristics of persons who died with COVID-19.—United States, February 12 – May 18, 2020. Morbidity and Mortality Weekly Report (MMWR), July 17, 2020; 69 (28): 923-929. https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e1.htm		
50. 8/23/2020	FDA issued an EUA for convalescent plasma on August 23, 2020. https://www.fda.gov/media/141477/download		
51. 8/23/2020	FDA News Release: FDA issues emergency use authorization for Convalescent Plasma as potential promising COVID-19 treatment, another achievement in Administration's fight against pandemic. U.S. Food & Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment		
	Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients as part of the agency's ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its decision memorandum , this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product.		
	Today's action follows the FDA's extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing.		
	The EUA authorizes the distribution of COVID-19 convalescent plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with COVID-19.		
	Alex Azar, Health and Human Services Secretary:		
	"The FDA's emergency authorization for convalescent plasma is a milestone achievement in President Trump's efforts to save lives from COVID-19," said Secretary Azar. "The Trump Administration recognized the potential of convalescent plasma early on. Months ago, the FDA, BARDA, and private partners began work on making this product available across the country while continuing to evaluate data through clinical trials. Our work on convalescent plasma has delivered broader access to the product than is available in any other country and reached more than 70,000 American patients so far. We are deeply grateful to Americans who have already donated and encourage individuals who have recovered from COVID-19 to consider donating convalescent plasma."		
	Stephen M. Hahn, M.D., FDA Commissioner:		
	"I am committed to releasing safe and potentially helpful treatments for COVID-19 as quickly as possible in order to save lives. We're encouraged by the early promising data that we've seen about convalescent plasma. The data from studies conducted this year shows that plasma from patients who've recovered from COVID-19 has the potential to help treat those who are suffering from the effects of getting this terrible virus," said Dr. Hahn. "At the same time, we will continue to work with researchers to continue randomized clinical trials to study the safety and effectiveness of convalescent plasma in treating patients infected with the novel coronavirus."		

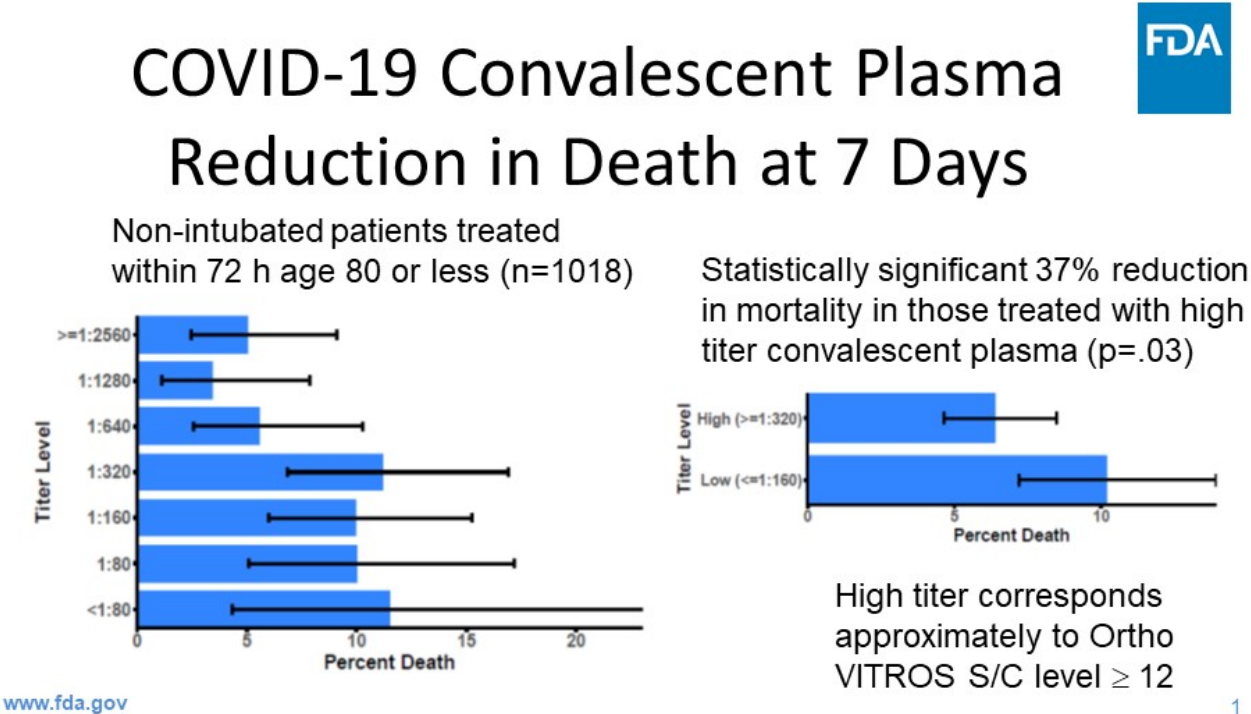
Scientific Evidence on Convalescent Plasma

Based on an evaluation of the [EUA criteria](#) and the totality of the available scientific evidence, the FDA’s Center for Biologics Evaluation and Research determined that the statutory criteria for issuing an EUA criteria were met.

The FDA determined that it is reasonable to believe that COVID-19 convalescent plasma may be effective in lessening the severity or shortening the length of COVID-19 illness in some hospitalized patients. The agency also determined that the known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product and that that there are no adequate, approved, and available alternative treatments.

The EUA is not intended to replace randomized clinical trials and facilitating the enrollment of patients into any of the ongoing randomized clinical trials is critically important for the definitive demonstration of safety and efficacy of COVID-19 convalescent plasma. The FDA continues to recommend that the designs of ongoing randomized clinical trials of COVID-19 convalescent plasma and other therapeutic agents remain unaltered, as COVID-19 convalescent plasma does not yet represent a new standard of care based on the current available evidence.

The EUA remains in effect until the termination of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of



Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.			
52. 8/23/2020	FDA Clinical memo	https://web.archive.org/web/20200823215842/https://www.fda.gov/media/141480/download	
53. 8/24/2020	Beachum L, Taylor A, Knowles H, Shammas B, Denham H, Kornfield, Thebault R: Scientists express doubts about coronavirus treatment touted as breakthrough by Trump. The Washington Post, August 24, 2020.	https://www.washingtonpost.com/nation/2020/08/24/coronavirus-covid-live-updates-us/	
54. 8/24/2020	MacGinley L, Abutaleb Y, Bernstein L: Some Trump Administrative claims on effectiveness of convalescent plasma are wrong or dubious, scientists say. The Washington Post, August 24, 2020.	https://www.washingtonpost.com/health/2020/08/24/some-administration-claims-effectiveness-convalescent-plasma-are-wrong-or-dubious-scientists-say/	
55. 9/1/2020	NIH: Statement on COVID-19 treatment guidelines.	https://web.archive.org/web/20200901235858/https://www.covid19treatmentguidelines.nih.gov/statement-on-convalescent-plasma-eua/	

The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of Convalescent Plasma for the Treatment of COVID-19

Last Updated: September 1, 2020

On August 23, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA)* for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19.^{1,2} The COVID-19 Treatment Guidelines Panel (the Panel) reviewed the available evidence from published and unpublished data on convalescent plasma for the treatment for COVID-19, including the FDA analyses that supported the EUA.

There are currently no data from well-controlled, adequately powered randomized clinical trials that demonstrate the efficacy and safety of convalescent plasma for the treatment of COVID-19. The FDA analysis of data on a subset of hospitalized patients from the Mayo Clinic's Expanded Access Program (EAP) compared outcomes in patients who received convalescent plasma with high titers of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) neutralizing antibodies to outcomes in patients who received plasma with low titers and found no difference in 7-day survival overall. Among patients who were not intubated, 11% of those who received convalescent plasma with high antibody titers died within 7 days of transfusion compared with 14% of those who received convalescent plasma with low antibody titers. Among those who were intubated, there was no difference in 7-day survival. Although these data suggest that convalescent plasma with high antibody titers may be beneficial in nonintubated patients, uncertainty remains about the efficacy and safety of convalescent plasma due to the lack of a randomized control group and possible confounding in the Mayo Clinic's EAP. Additionally, antibody levels in currently available COVID-19 convalescent plasma are highly variable, and assays to determine the effective antibody titers remain limited.³

Based on the available evidence, the Panel has determined the following:

- There are insufficient data to recommend either for or against the use of convalescent plasma for the treatment of COVID-19.
- Available data suggest that serious adverse reactions following the administration of COVID-19 convalescent plasma are infrequent and consistent with the risks associated with plasma infusions for other indications. The long-term risks of treatment with COVID-19 convalescent plasma and whether its use attenuates the immune response to SARS-CoV-2, making patients more susceptible to reinfection, have not been evaluated.
- Convalescent plasma should not be considered standard of care for the treatment of patients with COVID-19.
- Prospective, well-controlled, adequately powered randomized trials are needed to determine whether convalescent plasma is effective and safe for the treatment of COVID-19. Members of the public and health care providers are encouraged to participate in these prospective clinical trials.
- The Panel will continue to evaluate emerging clinical data on the use of convalescent plasma for the treatment of COVID-19 and will update the [Convalescent Plasma](#) section of the Guidelines in the near future.

* The criteria for issuance of an EUA are not the same as the standards for FDA approval.⁴ There are currently no FDA-approved therapies for the treatment of COVID-19.

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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References

1. Food and Drug Administration. Coronavirus disease 2019 (COVID-19) EUA information. 2020. Available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#euid19euas>. Accessed August 31, 2020.
2. Food and Drug Administration. Convalescent plasma letter of authorization. 2020. Available at: <https://www.fda.gov/media/141477/download>. Accessed August 31, 2020.
3. Food and Drug Administration. EUA 26382: Emergency Use Authorization (EUA) Request. 2020. Available at: <https://www.fda.gov/media/141480/download>. Accessed August 31, 2020.
4. Food and Drug Administration. Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders. January 2017; Available at: <https://www.fda.gov/media/97321/download>. Accessed August 31, 2020.

56. 9/2/2020 FDA: Recommendations for Investigational COVID-19 Convalescent Plasma. <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>

57.

58. Xxx

59. Xxx

60. Xxx

61.

9/2/2020 FDA: Recommendations for Investigational COVID-19 Convalescent Plasma. <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>

9/14/2020 Schneider G: In Kentucky visit, Dr. Deborah Birx says she has never “downplayed” Covid-19 risks. Louisville Courier Journal, September 14, 2020. <https://www.courier-journal.com/story/news/2020/09/14/covid-19-task-force-dr-birx-have-never-downplayed-coronavirus/5791067002/>

The physician said her team also is asking university leaders to consider launching additional antibodies tests, which are blood proteins that can indicate whether students and university staff already have had the virus and may be candidates for donating convalescent plasma. Antibodies-rich plasma has been shown to help critically ill patients fight off the infection.

9/21/2020 FDA Withdrawl of guidance: <https://www.regulations.gov/document?D=FDA-2020-D-1825-0011>

9/21/2020 Investigational COVID-19 Convalescent Plasma: Guidance for Industry; Availability. <https://www.regulations.gov/document?D=FDA-2020-D-1825-0001>

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
9/21/2020	Investigational COVID-19 Convalescent Plasma: Guidance for Industry https://www.regulations.gov/document?D=FDA-2020-D-1825-0002		.PDF hyperlink: Investigational COVID-19 Convalescent Plasma—Guidance for Industry, Document issued on September 2, 2020 .PDF hyperlink: <i>.PDF hyperlink:</i> Investigational_COVID-19_Convalescent_Plasma_Guidance_for_Industry%20(3).pdf also: https://www.fda.gov/media/136798/download

Fresh Frozen Numbers:

100 Whitaker BI, Rajbhandary S, Harris A: The 2013 AABB Blood Collection, Utilization, and Patient Blood Management Survey Report. American Association of Blood Banks, December 18, 2015. <http://www.aabb.org/research/hemovigilance/bloodsurvey/Documents/2013-AABB-Blood-Survey-Report.pdf>

101 Jones JM, Sapiano MRP, Savinkina AA, Haass KA, Baker ML, Henry RA, Berger JJ, Basavaraju SV: Slowing decline in blood collection and transfusion in the United States – 2017. Transfusion, March 2020; 60: S1 – S9.

62.

Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Yes / Positive	Maybe / Relative / Analog	No / Negative	Comments
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Attachment VII: Here are just a **few examples of aberrancies** in our applications during the American COVID-19 epidemic of:

- 1.) definitions and euphemisms,
- 2.) foundational principles and tenets and the pathophysiology of COVID-19,
- 3.) statistics and research terminology, and 4.)
- 4.) legal mandates

that we have violated, electronically overwritten, and destroyed-access-to-the-original-ULS that have sustained lies of commission, lies of omission, and paltering throughout American society during COVID-19:

1. Definitions:

- a. **Epidemic:** Infectious overwhelming contagious event within a location or a group of the population *versus* a **Pandemic** which is an expansive World-wide epidemic
- b. **Endogenous** versus **exogenous**
- c. **Treatment** versus **Cure**
- d. **Biologic** and **Drug**
- e. **Synergism** versus **Monotherapy** (the Magic Bullet):

1. **Synergy.** It is said that George Washington's vacuolization / variolization of the Continental Army troops with smallpox pustules facilitated final victory during the revolutionary war. William Jenner is attributed to having introduced / advocated for wide-spread vaccination with "cowpox" at the end of the eighteenth century. While the last documented case of smallpox in the United States was reported to have been in 1946. Yet, in the rest of the world, an endemic level of smallpox continued for another three decades with regional smallpox outbreaks. In the 1970s, the World Health Organization (WHO) proposed the elimination of this human-to-only-human-transmission virus through identification, isolation, tracking, and vaccination (*Active Immunization*). Knowing that persons already infected with smallpox would not respond immediately to vaccination, those that were infected or close contacts to those that were infected were treated first with exogenous immunoglobulins (convalescent plasma or sera) (*Passive Immunization*) so as to diminish the severity of illness in the individual and contain the spread of the smallpox virus within each regional locale. Epidemiologically, such a combination treatment strategies of *Active Immunization* and *Passive Immunization* that resulted in the eradication of smallpox from earth's population is an example of **Epidemiologic Synergy.**

2. As Monkey Pox (now called M Pox) is 90% homologous with smallpox, smallpox vaccine is felt to be protective – in fact, today the vaccine vials / packaging is labeled: in the treatment of smallpox and Monkey Pox—in reality, vaccination is *Active Immunization* while. As mandatory smallpox vaccinations were discontinued in 1982, in the United States today, about of the half the population is probably not completely immunologically naïve to M pox.

f. **Unidose vs Multidose Therapy**

g. **Treatment versus Cure**

h. Evidence Base Medicine

- a. RCT
- b. AMCT
- c. Ethics

i. **Legal Terminology**

- a. **EMTALA**
- b. **Right to Life**
- c. **Overwriting, changing of URLs, and Destruction of Documentation**
- d.

j. **sss**

k. Pathophysiology

l. **Immunology, Epidemiology, Treatment, and Prophylaxis of Infectious Diseases**

- m. **Epidemic:** Infectious overwhelming contagious event within a location or a group of the population *versus* a **Pandemic** which is an expansive World-wide epidemic

n. **Infectious Agents**

- a. Bacteria
- b. Viruses
- c. Prion diseases

o. **Humoral and Cell Immunity**

p. **Aa**

- a.

q. **Endogenous versus exogenous**

- r. Variolization, Vaccination
- s. Vaccines
- t. **Antibodies and Antigens**
- u. **Active Immunization:** Administration of exogenous specific antigens (Ag) by vaccination to produce endogenous antibodies (Abs) in the individual against those specific antigens (Ag). Normally, what is thought of as a vaccination, is a stimulation within the individual of B-cell development to produce endogenous antibodies (e.g: IgM, IgG, IgA) to specific Ags presented to the individual being vaccinated. In the individual, development of IgG against some Ag of the COVID-19 requires roughly two weeks for full effective immunologic response. With the time delay of the development of adequate amounts of endogenous IgG in the COVID-19 individual over two weeks, vaccination (Active Immunization) is *prophylaxis* not *treatment* of actively, acutely infected individuals as the most effectiveness time of IgG viral replication suppression is during the viremic phase of COVID-19 and not later during the time of cytokine cascade and bradykinin storm. Active immunization by systemic vaccines long-term acts through a complex cellular/humoral mechanism to address systemically the viremia early in the course of the disease (72-96 hours). In the case of respiratory viruses, nasal resistance to the SARS-CoV-2 virus is not protective due to systemic immunoglobins previously resultant from vaccination or previous systemic infection but is dependent on mucosal IgA, which requires only ~5 days after COVID-19 nasal exposure to reach adequate levels. This IgA protection is limited in proximity to the nares mucosa and has a short half-life long-term thus being ineffective for subsequent exposures without nasal reinoculation.
- v. **Passive Immunization:** Administration of exogenous antibodies to provide immediate systemic immunologic response (IgG). Application of passive immunization is *treatment* not *prophylaxis* when administered (within 72-96 hours of diagnosis) to an newly infected individual. (Passive immunization can be used as a prophylactic agent but administrations should be renewed every 8 weeks the concentration of exogenous antibodies diminish by ½ life decay. A naturally occurring form of Passive Immunization is the passage of maternal Abs across the placenta to the fetus). Passive immunization when given early has been the mainstay for the treatment of infections for over a century especially when pharmacologic antivirals are not available; and when antiviral pharmacologic agents are available, passive immunization can be used successfully synergistically. Convalescent plasma and sera, polyclonal antibodies, and monoclonal antibodies; γ -globulin, IVIG, etc.; and other specific plasmas and sera (Pasteur's rabies vaccine, hypertet, RhoGam, etc.) are all, variations of Passive immunization)
 - a. **Monoclonal versus Polyclonal Antibodies**

w. Vaccine Types**x. Pox viruses****y. ADE****z.****aa. Statistics****bb. Medical Statistics and Research Terminology**

- a. Independent variables Dependent variables
 - i. Time
 - ii. Age
 - iii. Direct initiation of treatment e.g: drug, biologic, operation, physical manipulation, or mechanical treatment
- b. Dependent variables
 - i. Life and Death
 - ii. Decrease in symptomatology, decrease in severity of illness, and “Cure”
 - iii. First and Second Order Kinetics
- c. Evidence Based Medicine
 - i. RCT
 - ii. AACT
 - iii. Others
- d. Outcomes/Results
 - i. End-points
 - ii. Exclusion v Inclusion
 - iii.
- e. FDA
- f. NIH
- g. NIAID
- h. Safety versus Efficacy – Phase I, II, III studies
- i. Expanded Access = Compassionate Use
- j. Approved versus Authorized
- k. EUA
- l. Evidence Based Medicine
- m. Randomized Controlled Studies
- n. Endpoints
- o. “Revoked”
 - i. **Medical Statistical definitions, postulates, and applications:** In clinical and research medicine, seldom is there a comparative

situation in which differences within a complete population can be measured and ascertained to be significant. In the simplest terms, medical statistics is a methodology of ascertaining (1) if a studied group is (“statistically”—which is redundant terminology) significantly different from a control group within the parameters of adequate sampling, (2) that the studied and controlled groups adequately represent the population, and, most of all, (3) the analyses avoid inherent bias. Seven decades ago, the best selling book: *How to Lie with Statistics* by Darrell Huff poked fun at our inherent inabilities to naïvely accept that which is not provable and, all too often, not true but are marketed as erroneous truths through our present day media, politics, publications, textbooks, etc. For decades in American media, one of the most “familiar” classic marketing examples that has no significance statistically but is touted seemingly as a truism was:

- ii. 4 out of 5 dentists recommend sugarless gum for those that chew gum!
- iii. While the mantra today is to strive for *Evidence Based Medicine*, the vast majority of medical studies published during the American COVID-19 epidemic were flawed as they had subliminal errors in statistical application and reasoning, incorrectly defined and applied nebulous endpoints, and, all too often, amplified statistical power and significance where there was none. All too often, today, the eagerness to confirm questionable theories, impatience to advance one’s personal assertions, and the race to quickly proclaim and publish have clouded that which is truly provable. Robert Condon, M.D., F.A.C.S. wrote about these foibles a half a century ago in an editorial entitled, *Type III Error*:
 1. Type I and type II errors are the two classic pitfalls in statistical analysis: finding a difference when there is none (type I) and failure to find a true difference (type II). There is, in addition, another important error that regularly appears in scientific journals. This error, *the type III error*, occurs whenever the conclusions drawn are not supported by the data present....
- iv. By defined medical standards, the **null hypothesis (H_0)** in the simplest terms means that when one compares two groups, A and B, then $A = B$. One can only reject the null hypothesis --thus stating that $A \neq B$ implying a statistical significance, if the comparison falls outside of a predesignated confidence level.
- v. While statistical boundaries are difficult to universally define, a segment of *Hypothesis Testing, P values, Confidence Intervals, and Significance* by Jacob Shreffler and Martin R. Huecker, NCBI

Bookshelf, a service of the National Library of Medicine, provide a succinct synopsis for clinical and research Medicine:

1. **Significance**

2. Significance is a term to describe the substantive importance of medical research. Statistical significance is the likelihood of results due to chance.[3] Healthcare providers should always delineate statistical significance from clinical significance, a common error when reviewing biomedical research.[4]. When conceptualizing findings reported as either significant or not significant, healthcare providers should not simply accept researchers' results or conclusions without considering the clinical significance. Healthcare professionals should consider the clinical importance of findings and understand both p values and confidence intervals so they do not have to rely on the researchers to determine the level of significance.[5]. One criterion often used to determine statistical significance is the utilization of p values.

3. **P Values**

4. P values are used in research to determine whether the sample estimate is significantly different from a hypothesized value. The p-value is the probability that the observed effect within the study would have occurred by chance if, in reality, there was no true effect. Conventionally, data yielding a $p < 0.05$ or $p < 0.01$ is considered statistically significant. While some have debated that the 0.05 level should be lowered, it is still universally practiced[6]. ...
5. While researchers have historically used p values, experts who find p values problematic encourage the use of confidence intervals.[8]. P-values alone do not allow us to understand the size or the extent of the differences or associations.[3]. In March 2016, the American Statistical Association (ASA) released a statement on p values, noting that scientific decision-making and conclusions should not be based on a fixed p-value threshold (e.g., 0.05). They recommend focusing on the significance of results in the context of study design, quality of measurements, and validity of data. Ultimately, the ASA statement noted that in isolation, a p-value does not provide strong evidence.[9] ...

6. **Confidence Intervals (CI)**

7. A confidence interval provides a range of values with give confidence (e.g., 95%), including the accurate value of the statistical constraint within a targeted population.[12]. Most research uses a 95% CI, but investigators can set any level (e.g., 90% CI, CI, 99% CI).[13]. A CI of 95% provides a range with the lower bound and upper bound limits of a difference or association that would be plausible for a population.[14]. Therefore, a CI of 95% CI, indicates that if a study were to be carried out 100 times, the range would contain the true value in 95,[15] confidence intervals provide more evidence regarding the precision of an estimate compared to p-values.[6]

- vi. In its simplest form, for the clinical application of a medical study in the development of the “p value”, the confidence interval, etc. in comparison 2x2 statistics, is expressed as **Sensitivity** and **Specificity**:

$$1. \text{ Sensitivity} = \frac{\text{(True positive)}}{\text{(True positive + False negative)}} \times 100$$

$$2. \text{ Specificity} = \frac{\text{(True negative)}}{\text{(True negative + False positive)}} \times 100$$

- vii. In the **DISCUSSION** that follows, the wholesale misapplication to these statistical concepts have amplified an uncertainty, confusion, and distrust towards American Medicine of the American people and throughout the world during our nation’s disordered addressing of COVID-19. Other of statistical concepts that are important in one’s assessment of the premise of this paper can be found in the following:

1. Independent variables versus dependent variables

2. Mean, Median, and Mode

3. Skewness

4. Exclusion versus Inclusion

5. Endpoints

6. Negative Results and their interpretations

7. Equilibrium

8. 1st order kinetics and Zero order kinetics

9. Half-life

cc. Marketing (including rationing)

- dd. The **RESULTS** section of this paper will provide examples of omissions, paltering, short-comings, misdirections, and lies during the United States COVID-19 epidemic. It will point out violations of foundational tenets, their applications, and analyses in Clinical Medicine--especially in Immunology. The RESULTS section of this paper will address perceived allegations of disregard, misinterpretation, and paltering of Federal policies, directives, etc. that have led to a leaderless confusion in the appropriate assessment and application of the principles of Immunology, Pharmacology, and Clinical Medicine. A few areas of inappropriate interpretation(s) and misapplication(s) contributory to our nation's confusion regarding Clinical Medicine and our fight against COVID-19 includes:
- ee. the lack of pathophysiology-directed treatment of coronavirus,
- i. SARS-CoV-2 (COVID-19) throughout the last four years and ongoing;
- ff. the unilateral focus on prophylaxis—rather than more comprehensive synergistic
- i. protocols of early treatment (not just prophylaxis) with immunotherapy and antivirals regardless of concomitant of diseases and age-related maladies in individual patients which has led to (and continues to direct) *de facto* rationing by selective inclusion only and inappropriate exclusion otherwise of individuals infected with coronavirus, SARS-CoV-2;
- gg. abandonment of basic medical statistics such as the null hypothesis (H_0), the
- i. absolute distinctions between independent and dependent variables, disregard for the significance or lack of significant insensitivity and specificity, confidence levels, and endpoints—primary versus secondary, etc.
- hh. subsequent and ongoing violation of patients' rights and equity by preventing the COVID-19 infected individual
- i. to request and receive immunologic and antiviral treatments (not just prophylaxis) during the early phase of viremia (~72 – 96 hours from diagnosis) rather than the latter phases of cytokine cascade and bradykinin storm.

- 2. Foundational Concepts**
- 3. Research and Statistical tenets and terminology**
- 4. Laws**

Table 2: Chi-square analysis of Figure 1 of NEJM article, November 18, 2021

Early Convalescent Plasma for High-Risk Outpatients with Covid-19 palteristically concluded in its abstract's conclusion:

The administration of Covid-19 convalescent plasma to high-risk outpatients within 1 week after the onset of symptoms of Covid-19 did not prevent disease progression. (SIREN-C3PO ClinTrials.gov number, NCT04355767).

Contrary to the above statement, a 2x2 contingency table and Chi-square analysis of the hierarchal figure on page 1955 of the November 18, 2021, NEJM edition, entitled: Figure 1. Enrollment, Randomization, and Analysis Populations., yields an outcome that is not (statistically) significant: **Table 2: Chi-square analysis of Figure 1 of NEJM article, November 18, 2021:**

Contingency	NEJM Paper Figure 1		
	↩		
Table Analyzed	Data 1		
P value and statistical significance			
Test	Fisher's exact test		
P value	0.1224		
P value summary	ns		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	No		
Data analyzed	Lived	Died	Total
CCP	243	5	248
Placebo	248	1	249
Total	491	6	497
Percentage of row total	Lived	Died	
CCP	97.98%	2.02%	
Placebo	99.60%	0.40%	
Percentage of column total	Lived	Died	
CCP	49.49%	83.33%	
Placebo	50.51%	16.67%	
Percentage of grand total	Lived	Died	
CCP	48.89%	1.01%	
Placebo	49.90%	0.20%	

Table 3:

Table 3: Chi-square Analysis of NEJM Article’s Non-Representation of the U.S. Population by Age-adjusted Mortality

Contingency	Chi-square Included v Excluded-	Lived v Died for ≥ 50 yr old	
Table Analyzed	Data 1		
P value and statistical significance			
Test	Fisher's exact test		
P value	<0.0001		
P value summary	***		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	Yes		
Data analyzed	Lived	Died	Total
Included	491	6	497
Excluded	3041	452	3493
Total	3532	458	3990
Percentage of row total	Lived	Died	
Included	98.79%	1.21%	
Excluded	87.06%	12.94%	
Percentage of column total	Lived	Died	
Included	13.90%	1.31%	
Excluded	86.10%	98.69%	
Percentage of grand total	Lived	Died	
Included	12.31%	0.15%	
Excluded	76.22%	11.33%	

Contingency	Chi-square Included v Excluded-	Lived v Died for mean 60 yr old	
Table Analyzed	Data 3		
P value and statistical significance			
Test	Fisher's exact test		
P value	<0.0001		
P value summary	***		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	Yes		
Data analyzed	Lived	Died	Total
Included	491	6	497
Excluded	2659	634	3293
Total	3150	640	3790
Percentage of row total	Lived	Died	
Included	98.79%	1.21%	
Excluded	80.75%	19.25%	
Percentage of column total	Lived	Died	
Included	15.59%	0.94%	
Excluded	84.41%	99.06%	
Percentage of grand total	Lived	Died	
Included	12.96%	0.16%	
Excluded	70.16%	16.73%	

Contingency	Chi-square Included v Excluded-	Lived v Died for mean 70 yr old	
Table Analyzed	Data 4		
P value and statistical significance			
Test	Fisher's exact test		
P value	<0.0001		
P value summary	***		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	Yes		
Data analyzed	Lived	Died	Total
Included	491	6	497
Excluded	2677	816	3493
Total	3168	822	3990
Percentage of row total	Lived	Died	
Included	98.79%	1.21%	
Excluded	76.64%	23.36%	
Percentage of column total	Lived	Died	
Included	15.50%	0.73%	
Excluded	84.50%	99.27%	
Percentage of grand total	Lived	Died	
Included	12.31%	0.15%	
Excluded	67.09%	20.45%	

Contingency	Chi-square Included v Excluded-	Lived v Died for mean 80 yr old	
Table Analyzed	Data 5		
P value and statistical significance			
Test	Fisher's exact test		
P value	<0.0001		
P value summary	***		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	Yes		
Data analyzed	Lived	Died	Total
Included	491	6	497
Excluded	2496	997	3493
Total	2987	1003	3990
Percentage of row total	Lived	Died	
Included	98.79%	1.21%	
Excluded	71.46%	28.54%	
Percentage of column total	Lived	Died	
Included	16.44%	0.80%	
Excluded	83.56%	99.40%	
Percentage of grand total	Lived	Died	
Included	12.31%	0.15%	
Excluded	62.56%	24.99%	

Table 4: Updated Evidence to Support the Emergency Use of COVID-19 Convalescent Plasma – as of 9/23/2024

Updated Evidence to Support the Emergency Use of COVID-19 Convalescent Plasma – as of 9/23/2020										
BEST ITERATIONS										
	7-day									
	Lived		Death		p value	Lived		Death		p value
	7-day	Survival	7-day	Mortality		28-day	Survival	28-day	Mortality	
Low titer Not Intubated	1002	86.08%	162	13.92%	1164	312	50.24%	309	49.76%	621
High titer Not Intubated	1178	88.97%	146	11.03%	1324	360	58.35%	257	41.65%	617
	2180		308		2488	672		566		1238
FDA reported					0.03					0.004
Iterated					0.0326					0.0044
	Lived		Death		p value	Lived		Death		p value
	7-day	Survival	7-day	Mortality		28-day	Survival	28-day	Mortality	
Low titer Not Intubated, ≤80 y, ≤72 h	408	88.70%	52	11.30%	461	130	53.50%	113	46.50%	243
High titer Not Intubated, ≤80 y, ≤72 h	442	93.64%	30	6.36%	471	161	66.53%	81	33.47%	242
	850		82		932	291		194		485
FDA reported					0.008					0.004
Iterated					0.0079					0.004
https://www.fda.gov/media/142386/download										

Table 5: Table of Serious Adverse Event (SAE) Reporting

Table 5: Serious Adverse Events	Transfusion-associated adverse reactions in the USA, 2021	Reactions per 100,000	Percent adverse reactions per all blood therapies transfused		Transfusion-associated adverse reactions in FDA/Mayo Clinic CCP protocol, n= 20,000	Percent adverse reactions in FDA/Mayo Clinic CCP protocol, n= 20,000	
Total number of reactions that required any diagnostic or therapeutic intervention	45,142	0.002738	0%				
TRALI	192	0.000011	0.0011%		21	0.105%	
TACO	2491	0.000147	0.0147%		36	0.180%	
Allergic reactions							
Mild to moderate	12,010	0.000714	0.0714%				
Severe	427	0.000025	0.0025%		21	0.105%	
Anaphylactic reactions							
Febrile nonhemolytic reactions	18,918	0.18918	18.92%				
Hemolytic reactions							
Hypothermia							
Metabolic							
Transmission of Infectious pathogens							
bacterial	57	0.0000034	0.000340%				
viral	11	0.00000064	0.000064%				
parasitic	4	0.00000023	0.000023%				
Thrombotic events					113	0.565%	
			38 thrombotic events	deemed related to CCP transfusion			
					38	0.190%	
FDA/Mayo Clinic CCP Protocol with 20,000 CCP hospitalized patients							p value
Mortality within 4 hours of transfusion of					63	0.315%	
			10 mortalities within 4 hrs of transfusion	deemed related to CCP			
					10	0.050%	
Mortality-- 7 day							
Low titer, not intubated, <80 y, <72 hr					52 of 932	5.579%	0.004
High titer, not intubated, ≤80 y, ≤72 hr					30 of 932	3.219%	
Mortality-- 28 day							
Low titer, not intubated, <80 y, <72 hr					113 of 485	23.299%	0.004
High titer, not intubated, <80 y, <72 hr					81 of 485	16.701%	

Table 6: 7.0 2021-09-19 Timeline of U.S. Government Regarding Passive Immunization and the Discrediting of COVID-19 Convalescent Plasma

Dear Mr. President:

Please excuse my forwardness in submitting this cover letter to you but it is of major importance and my duty as a federal physician to appraise you of this. As Dr. Birx said in her interview with Margaret Brennan on face the nation on January 24, 2021, timelines like this may never come out in her lifetime. The bottom line is that US medicine and the Executive Branch of the Federal Government in March 2020, abandoned the America people by NOT offering **Passive Immunization** as the immediately available treatment of COVID-19, future synergistic treatment with **Active Immunization** in all that contract COVID-19 after vaccination, and a prophylaxis for high-exposure individuals like healthcare workers, first responders, grocery clerks, immune suppressed individuals and everyone else. The timeline of the failure of U.S. Medicine, U.S. Research, and the U.S. Government regarding **Passive Immunization** in the form of COVID-19 Convalescent Plasma (CCP) can be found in this timeline that follows:

1. On March 3/2/2020, leaders of Pharma, the FDA, the NIH, etc. met with President Trump and failed to make the distinction of **Active Immunization versus Passive Immunization**. https://www.youtube.com/watch?v=31i6p_stzW8
2. President Trump declared an emergency on March 13, 2020. <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>
3. Secretary Azar on March 13, 2020 suspended parts of EMTALA retroactive to March 1, 2020. <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>
4. China sends medical team to Italy to set up 50 blood collection centers to help in treatment of COVID-19. <https://www.chinadaily.com.cn/a/202003/14/WS5e6bd352a31012821727f096.html>
5. On March 19, 2020, Johns Hopkins Bloomberg School of Public Health carries story of China offering to Italy 90 tons of COVID-19 Convalescent Plasma (~500,000 doses). <https://www.globalhealthnow.org/2020-03/covid-19s-stop-gap-solution-until-vaccines-and-antivirals-are-ready>
6. On March 24, 2020, **FDA Failure because** instead of the FDA declaring **Passive Immunization** synergistic with future vaccination (active immunization--vaccination) and declaring convalescent plasma (a Nobel Prizing winning passive immunization, 1901) a biosimilar biologic to e.g.: rabies vaccine, RhoGAM gamma globulin, IVIG, tetanus hyper immune globulin, etc., the FDA **declared COVID-19 convalescent plasma investigational**. (i.e.: **EXPERIMENTAL**)

- https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf
7. In order to make convalescent plasma immediately available the FDA authorized **expanded access (COMPASSIONATE USE)** through six programs in the United States WITH most visible that through the Mayo Clinic in which over >2700 hospitals would participate.
<https://web.archive.org/web/20200404010134/https://www.uscovidplasma.org/> By the definitions of the NIH and FDA “Expanded Access” is “Compassion Use” (DATA **NOT AVAILABLE TO BE USED FOR CLINICAL TRIALS**) which means that any data from the administration of over 94,000 doses by the Mayo Clinic from March 24, 2020 to EUA of August 23, 2020 should not have been used as data for research studies. (The vast majority of **CCP administrations were given late in the disease at the WRONG TIME.**)
 8. On March 24, 2020 the FDA announced inclusion criteria for administration of COVID-19 convalescent plasma which was wrong giving it only when the patients were on death’s door with the FDA referencing their misinterpretation of an Chinese epidemiology paper published in February 2020. (**The FDA removed the reference in all subsequent documentations and failed to tell the American public they were administering CCP at the WRONG time.** The FDA quietly removed the WRONG inclusive criteria from all subsequent documentation on September 2, 2020.) Passive immunization has only been shown to be most successful in previous epidemics when given within the first 72 hours of diagnosis—NOT at death’s door!
https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf
 9. **For the last 18 months the FDA has made all the agents of passive Immunization experimental (Investigational) by issuing EUAs.** In so doing they violated the intent (and really the letter of the law) of PL-115-176, the Right to Try Law
<https://www.govinfo.gov/content/pkg/PLAW-115publ176/pdf/PLAW-115publ176.pdf> in limiting the ability of patients to request **Passive Immunization** agents –thus, abandoning / withholding treatment of the American people within 72 hours of contracting COVID-19.
 10. CCP was issued its first EUA on August 23, 2020 while still under the restrictive late-in-the-disease inclusion criteria of March 24, 2020. The FDA quietly rescinded this wrong inclusion criteria on September 2, 2020 and then did not notify the American public. (The FDA also quietly rescinded the same inappropriate inclusion criteria regarding Remdesivir on August 28, 2020.). President Trump in the first 2 minutes of the White House Press Conference insulted China by referring to the coronavirus SARS-CoV-2 virus as the **CHINA virus**. (China stopped their epidemic by quarantine and liberal use of CCP. How does one know this?--In March 2020, China sent 15 medical personnel to Italy to assist in the development of CCP infusion centers and **China offered 90 tons of surplus CCP to the Italians.**)

11. October 2, 2020 President Trump was diagnosed with COVID-19, and within four hours President Trump was given Regeneron monoclonal antibody cocktail and within 18 hours began Remdesivir infusions. Subsequently, it is documented that former Governor Christie, former Mayor Giuliani, and former HUD Secretary Dr. Ben Carson received at least monoclonal antibodies. **While every person in the United States who turned positive for COVID-19 should have been eligible for early administration of this combination of monoclonal antibodies and Remdesivir, it was concealed in plain sight** from the American people by agencies of the Executive Branch of the Federal Government by not announcing its significance formally to the American people.
12. In November 2020 the VA issued the incorrect timely--administration inclusion criteria for Remdesivir (Velkury), which had been approved as a prescription drug on October 22, 2020 by the FDA. The VHA still lists this incorrect administration criteria continuing to this day on the Internet to this day. At the time, I was in e-mail communications with VHA Chief Medical Executive, Richard Stone, M.D., (really VHA Under Secretary of Health although I am not sure he was approved by Congress) and *The New England Journal of Medicine*.
13. On January 6, 2021, *The New England Journal of Medicine* published the **only prospective, randomized, placebo-controlled, appropriately timed (<72 hours from diagnosis administration), age-stratified CCP administrated article** for the last 18 months. This "landmark" article definitively demonstrated that when CCP was administered early (<72 hours from time of diagnosis) and compared with placebo in 70 year old patients, the decrease in hospitalization was significant ($p < 0.03$) and the morality was halved (CCP=2 vs. placebo=4) but did not reach significance as the study was too small.
14. On January 24, 2021, Dr. Birk's was interviewed by Margaret Brennan on *Face the Nation*. <https://www.youtube.com/watch?v=odkIJGnhvhU>
15. On February 1, 2021, I e-mailed the FDA, NIH, *The New England Journal of Medicine*, and many pertinent persons (*reducio-ad-absurdum*) pointing out Dr. Birk's plea.
16. On February 4, 2021, the chief scientist of the FDA, RADM Denise Hinton issued a new EUA for Convalescent Plasma (*vis-a-vis* coinciding within 48 hours of my letter to Dr. Birk).
17. Within 24 hours, Peter Marks, M.D., Chief of the Biologic Division of the FDA is quoted in the WSJ with conflicting remarks about convalescent plasma. He then issues an official statement from the FDA and in an interview three weeks later praising CCP.
18. In the NEJM on February 18, 2021, Dr. Katz Acting Director of the Mississippi Valley Blood Authority (now renamed ImpactLife) prints a three page light-hearted,

obfuscating editorial entitled: (A Little) clarity on convalescent plasma for COVID-19.

19. In February 2021, BARDA announces it will defund CCP throughout the nation.
 20. March 8, 2021, ImpactLife to phase out CCP donations (~120 hospitals in the Midwest)⁴⁸⁴
 21. The NIH quotes an underpowered study (results not published) regarding a non-age-stratified placebo-controlled ER study on CCP administration that was closed early because they could not recruit even patient's for the placebo study.
 22. March 10, 2021: Convalescent Plasma Strikes Out as COVID-19 Treatment.
<https://www.npr.org/sections/health-shots/2021/03/10/975365309/convalescent-plasma-strikes-out-as-covid-19-treatment>
 23. April 21, 2021: NIH COVID-19 Treatment Guidelines panel recommends against COVID-19 Convalescent Plasma.
<https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/convalescent-plasma/>
 24. Regeneron teams up with ROCHE International to market REG-CoV-2 (monoclonal cocktail to the world). (ROCHE is selling REG-CoV-2 to hospitals in India for 50,000 Repees (~\$800) for those that can afford it to be given early in the course of the disease. On-the-street it is referred to as the "Trump cocktail")
- this is incomplete but will be submitted as it is an extensive timeline on how COVID-19 Convalescent Plasma was discredited, 10/20/2021

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33. Department of Health and Human Services, Food and Drug Administration: Development of therapeutic protein biosimilars: Comparative analytical assessment and other quality-related consideration; Draft guidance for Industry; Availability. Docket No. FDA-2019-D-2102. Federal Register 2019 May 22; 84(99): 23569-23571.
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FDA COVID-19 Convalescent Plasma Guidance for industry

36. 2/24/2020 Wu Z, McGoogan JM: Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) Outbreak in China: Summary of a report of 72314 cases from the Chinese Center for Disease Control and Prevention. JAMA. Published online February 24, 2020. Doi:10.1001/jama.2020.2648.
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37. 3/24/2020 Investigational COVID-19 Convalescent Plasma – Emergency INDs.
https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf or
https://natap.org/2020/COVID/032320_39.htm
FDA: Investigational COVID-19 Convalescent Plasma – Emergency INDs. “A licensed physician must request the Emergency IND (eIND) and obtain the COVID-19 convalescent plasma from a blood center. FDA does **not** provide COVID-19 convalescent plasma for eINDs. Investigational COVID-19 Convalescent Plasma – Emergency INDs Frequently Asked Questions (/media/136470/download).

U.S. Food and Drug Administration: Investigational COVID-19 Convalescent Plasma – Emergency INDs, March 24, 2020.

https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf

- **Eligible patients for use under expanded access provisions:**
 - Must have laboratory confirmed COVID-19
 - Must have severe or immediately life-threatening COVID-19, for example:¹
 - Severe disease is defined as:
 - dyspnea,
 - respiratory frequency ≥ 30 /min,
 - blood oxygen saturation $\leq 93\%$,
 - partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300 , and/or
 - lung infiltrates $> 50\%$ within 24 to 48 hours
 - Life-threatening disease is defined as:
 - respiratory failure
 - septic shock, and/or

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-ind-27-3-2020>

27/3/2020 Investigational COVID-19 Convalescent Plasma - Emergency INDs | FDA

- multiple organ dysfunction or failure
- Must provide informed consent

¹Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. *JAMA*. Published online February 24, 2020. doi:10.1001/jama.2020.2648

NO WHERE in the aforementioned reference #1 by Wu and McGoogan upon which officially the U.S. FDA based the *Eligibility Criteria* for administration of COVID-19 Convalescent Plasma from March 24, 2020 to September 2, 2020 is “CONVALESCENT”, “PLASMA”, “ELIGIBILITY” or “CRITERIA” mentioned even once !!!!

2020-03-24 Investigational COVID-19 Convalescent Plasma – Emergency INDs. (This is the NATAP Verbatim internet copy of reference 28 in its entirety that I have copied and pasted verbatim to follow from https://natap.org/2020/COVID/032320_39.htm as this is an original copy I can find on the Internet which is of the FDA's directive of March 24, 2020 that directed all the *misdirection based on only one reference #1 by Zunyou Wu, M.D., PhD, Jennifer M. McGoogan, PhD which never mentions COVID-19 Convalescent Plasma nor recommends* the eligibility criteria justifying the FDA authorizations of COVID-19 Convalescent Plasma (CCP), and EUs that were to follow in the next 10 months.)

PLEASE NOTE THAT WEB SITE REFERENCED JUST BELOW MARCH 24, 2020
<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-ind-27-3-2020> IS A HYPERLINK THAT BECAUSE OF THE FDA OVERWRITING PRACTICES AS PERMITTED BY THAT WHICH WAS PUBLISHED IN THE *FEDERAL REGISTER* on March 25, 2020 now points *ex post facto* to the future FDA website: Recommendations for Investigational COVID-19 Convalescent Plasma, February 11, 2021, and then with each overwrite *ad infinitum*. (Today, 12/13/2024, the last overwritten document is dated January 10, 2022. (One can trace back the referenced website with modifications using the Internet Archive (Wayback Machine -- <https://archive.org/web/>) to April 8, 2020. The FDA version of the verbatim document below must have been referenced between March 24, 2020 to ~April 8, 2020 was electronically replaced so that media articles (listed below) referencing the March 24, 2020 announcement *ex post facto* references to April 8, 2020 NO LONGER EXIST.

*I, therefore, allege that there was **Blatant Misdirection** of the official FDA documentation of March 24, 2020 in which the **Eligibility Criteria** is wrongly attributed to reference #1 which initiated the administration of CCP TO ONLY EXTREMELY ILL INDIVIDUAL PATIENTS AT THE **WRONG TIME** (not during the early viremic phase or prophylactically) which was probably a **Federal Criminal Offense** by someone in the FDA, Department of Health and Human Services, and/or *The White House*.*

I allege, on behalf of the American people, this misdirection of official federal FDA documentation facilitated: 1) misdirected CCP application at an inappropriate (wrong) late-in-time in the course of the disease in >700,000 individuals having contracted COVID-19 and having developed life-threatening systemic complications (e.g., bilateral pneumonitis, kidney failure, etc.); 2) promoted nonsensical, inappropriate medical research/NIH ClinicalTrials (<https://www.clinicaltrials.gov/> of CCP at the wrong administration time); 3) promoted violation of PL-115-176--*The Right to Try Law*--by promoting NON Completion of Phase I Studies; 4) promoted CCP application late in the individual's COVID-19 disease (which is the **WRONG TIME** to administer *Passive Immunization*); 5) led to the *de facto* discrediting of *Passive Immunization* as a treatment; 6) promoted *de facto* physician abandonment of their individual COVID-19 positive patients early in the course of the individual's disease (viremic phase); and 7) inadvertently led to greater than a half-of-a-million American deaths!

Below, copied and pasted *verbatim* from the National AIDS Treatment Advocacy Project (NATAP) https://natap.org/2020/COVID/032320_39.htm is the original NATAP copy found of the FDA's directive of March 24, 2020 that directed the **misdirection** regarding the eligibility criteria, FDA authorizations of COVID-19 Convalescent Plasma (CCP), and EUAs that were to follow for the next 10 months.

Investigational COVID-19 Convalescent Plasma - Emergency INDs

38. 3/25/2020. Lessa F: FDA: Investigational COVID-19 Convalescent Plasma – Emergency investigational new drug applications. Regional Platform on Access and Innovation for Health Technologies^{SPRAIS}, Pan American Health Organization, World Health Organization. March 25, 2020. <https://prais.paho.org/en/fda-investigational-covid-19-convalescent-plasma-emergency-investigational-new-drug-applications/>

4/3/2020 Investigational COVID-19 Convalescent Plasma – Emergency INDs (could no longer be found on the Internet—therefore have scanned this document of April 3, 2020 with my response letters to Dr. Fauci and Hahn and the President with USPS documentation of mailing into pdf file: 04 Scan of 4_3_20 Investigational CCP FDA Emerg INDs.pdf)

39. 3/26/2020 Hopkins Tanne J: Covid-19: FDA approves use of convalescent plasma to treat critically ill patients. BMJ 2020; 368:m1256 doi: 10.1136/bmj.m1256 (Published 26 March 2020). <https://www.bmj.com/content/bmj/368/bmj.m1256.full.pdf>

Dear Mr. President: *I apologize for copying and pasting the following excerpted as this is copyright protected material by the BMJ Publishing Group Limited but I am presenting this to you as **Educational Material** BUT the URL to which the references point were changed by the FDA so that the eligible criteria justifying reference “1” of March 24, 2020 is extremely difficult to find: Wu Z, McGoogan JM. Characteristics of and Important Lessons from the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72,314 Cases from the Chinese Center for Disease Control and Prevention. JAMA. Published online February 24, 2020. –C. Andrus, M.D.*

Plasma from people who have recovered from covid-19 may contain antibodies to the virus that causes the disease and might be effective against the infection, the FDA said. Convalescent plasma has been studied in outbreaks of other respiratory infections, such as H1N1 influenza, SARS, and MERS. “Although promising, convalescent plasma has not been shown to be effective in every disease studied” and therefore clinical trials were needed to see if it was useful in covid-19, the FDA cautioned.

The FDA told doctors wanting to study the use of convalescent plasma to follow the usual system for an investigational new drug (IND) application.

The plasma must be collected from recovered patients who can donate blood, have had no symptoms for 14 days, and have had negative results on covid-19 tests.

However, given the current public health emergency, the FDA said it was providing emergency access to convalescent plasma for patients “with serious or immediately life threatening covid-19 infections.”

Severe disease is defined as dyspnoea, respiratory frequency ≥ 30 breaths per minute, blood oxygen saturation $\leq 93\%$, ratio of arterial partial pressure of oxygen to fraction of inspired oxygen ($\text{PaO}_2 / \text{FiO}_2$) 50% within 24 to 48 hours.

Life threatening disease is defined as respiratory failure, septic shock, or multiple organ dysfunction or failure. In such cases, doctors can submit a form online or call FDA’s hotline telephone number (1-866-300-4374) to get verbal approval for treatment, which is promised within four to eight hours.

Jeffrey Henderson of Washington University School of Medicine in St Louis, Missouri, told National Public Radio, “The FDA just opened the floodgates. Our institution is scrambling to be ready to use this. There are many others, I’m sure.”³

1 FDA. Investigational covid-19 convalescent plasma—emergency INDs. <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ideprocess-cber/investigational-covid-19-convalescent-plasma-emergency-ind>

2 Hixenbaugh M. FDA will allow doctors to treat critically ill coronavirus patients with blood from survivors. NBC News 2020 Mar 24. www.nbcnews.com/news/us-news/fda-will-allow-doctors-treat-critically-ill-coronavirus-patients-blood-n1167831

3 Palca J. FDA expedites treatment of seriously ill covid-19 patients with experimental plasma. National Public Radio, 24 Mar 2020. www.npr.org/sections/coronavirus-liveupdates/2020/03/24/820939536/fda-expedite-treatment-of-seriously-ill-covid-19-patients-with-experimental-plasma

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40. 4/1/2020 approval of the FDA/Mayo Clinic COVID-19 Expanded Access Program:

Senefeld JW, Johnson PW, Kunze KL, Bloch EM, van Helmond N, Golafshar MA, Klassen SA, Klompas AM, Sexton MA, Diaz Soto JC, Grossman BJ, Tobian AAR, Goel R, Wiggins CC, Bruno KA, van Buskirk CM, Stubbs JR, Winters JL, Casadevall A, Paneth NS, Shaz BH, Petersen MM, Sachais BS, Buras MR, Vassallo RR, Shepherd JRA, Young PP, Verdun NC, Marks P, Haley NR, Rea RF, Katz L, Herasevich V, Waxman DA, Whelan ER, Bergman A, Clayburn AJ, Grabowski MK, Larson KF, Ripoll JG, Anderden KJ, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Buchholtz ZA, Peltsch MC, Wright K, Greenshields JT, Joyner MJ, Wright RS, Carter RE, Fairweather D: Access to and safety of COVID-19 convalescent plasma in the United States Expanded Access

Program: A national registry study. PLoS Med 2021 December 20; 18(12): e1003872.
<https://doi.org/10.1371/journal.pmed.1003872>

41. 4/4/2020 Joyner M, (Principal Investigator): COVID-19 expanded access program—Convalescent Plasma COVID-19 (coronavirus) Treatment—Mayo Clinic. This is the first date of the preservation of the website by the *Internet Archive* (Wayback Machine). Origin of the FDA/Mayo Clinic expanded access program. **(An expanded access program is for “compassionate use” only—and thus cannot be used as a Randomized Controlled Trial by the definitions of the NIH and the FDA)**
<https://web.archive.org/web/20200404010134/https://www.uscovidplasma.org/>

The protocol requires the patient or family member to consent to receiving plasma from someone who has recovered from COVID-19. Their plasma has substances that could improve chances of recovery. Only hospitalized patients referred by their health care provider will participate in this protocol.

Hospitalized patients are eligible to receive convalescent plasma if:

- They are 18+ years of age
- They have laboratory-confirmed diagnosis of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19
- They are admitted to an acute care facility for the treatment of COVID-19 complications
- They have severe or life-threatening COVID-19, or judged by the treating provider to be at high risk of progression to severe or life-threatening disease
- There is informed consent provided by the patient or healthcare proxy

Severe COVID-19 is defined by one or more of the following:

- Shortness of breath (dyspnea)
- Respiratory frequency $\geq 30/\text{min}$
- Blood oxygen saturation $\leq 93\%$
- Partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300
- Lung infiltrates $> 50\%$ within 24 to 48 hours

Life-threatening COVID-19 is defined as one or more of the following:

- Respiratory failure
- Septic shock
- Multiple organ dysfunction or failure

Michael J. Joyner, M.D., Summary, Mayo Clinic.
<https://www.mayo.edu/research/faculty/joyner-michael-j-m-d/bio-00078027>

42. 4/7/2020 Rivera N: Medical Task Force COVID-19 (Puerto Rico): Investigational COVID-19 Convalescent Plasma Emergency Investigational New Drug, Date April 7, 2020. <https://covid19tf.rcm.upr.edu/wp-content/uploads/sites/45/2020/04/Protocolo28->

[Convalescent-Plasma-1.pdf](https://web.archive.org/web/20201024144129/https://covid19tf.rcm.upr.edu/wp-content/uploads/sites/45/2020/04/Protocolo28-Convalescent-Plasma-1.pdf) (This site can't be reached directly). This can be viewed at <https://web.archive.org/web/20201024144129/https://covid19tf.rcm.upr.edu/wp-content/uploads/sites/45/2020/04/Protocolo28-Convalescent-Plasma-1.pdf>

Since only limited data exists at this moment regarding the effectiveness of this therapy, it cannot be routinely recommended or used as a proven treatment option. The Food and Drug Administration (FDA) has provided several pathways to administer or study the use of convalescent plasma in COVID-19 patients:

- Clinical Trials: Investigators wishing to study the use of convalescent plasma need to submit a request to FDA for investigational use under the traditional IND regulatory pathway (21 CFR 312).
- Expanded Access: FDA is working with multiple federal partners and academia to open an expanded access protocol to facilitate access to COVID-19 convalescent plasma. For patients with, or at risk of, severe or life-threatening COVID-19 disease who are not eligible or who are unable to participate in randomized clinical trials, access may be available through participation of acute care facilities in an investigational expanded access protocol under an IND already in place.
- Single Patient Emergency IND: For patients who are not able to participate in a clinical trial or in an expanded access program, given the public health emergency FDA also is facilitating access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of the patient's physician requesting a single patient emergency Investigational New Drug Application (eINDs) for the individual patient under 21 CFR 312.310. This process allows the use of an investigational drug for the treatment of an individual patient by a licensed physician upon FDA authorization. This eIND process is not for the use of COVID-19 convalescent plasma for the prevention of infection.

43. 4/8/2020 FDA: Recommendations for Investigational COVID-19 Convalescent Plasma. <https://web.archive.org/web/20200408215026/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma> which hyperlinked on 4/8/2020 to that which follows on 4/14/2020:

44. 4/14/2020 FDA first document of Guidance for industry: <https://web.archive.org/web/20200414181056/https://www.fda.gov/media/136798/download>

45. 4/17/2020 Langi DM, Jr., De Santis GC, Bordin JO: Covid-19 convalescent plasma transfusion. *Hematol Transfus Cell Ther.* 2020 Apr-Jun; 42(2): 113 – 115. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7164882/pdf/main.pdf>

... Therefore, all therapeutic options for the potentially lethal COVID-19 infection must be discussed ethically and scientifically. Historically, convalescent plasma (CP), a passive immunotherapy, has been used as a possible therapeutic option when no proven specific vaccine or drug is available for emerging infections.^{1,2} The administration of convalescent plasma or immunoglobulins has been shown to shorten the hospital stay and reduce the mortality rate in patients with SARS who did not respond to methylprednisolone in uncontrolled non-randomized clinical trials.^{3,4} Cheng et al. investigated 1775 SARS patients and found that 80 patients transfused with SARS convalescent plasma had a lower mortality rate, compared to non-transfused patients (12.5% vs. 17%).⁴

Conclusions:

Analogous to the SARS, the COVID-19 infection progresses with an intense inflammatory response that eventually causes serious lung damage, increasing the mortality risk. In the absence of a definitive curative management, many treatment algorithms have been explored in the treatment of the COVID-19. Among possible interventions, the use of plasma collected from recovered patients shows an initial promise, however published results of rigorous clinical trials are needed before we may draw definitive effectiveness conclusions on this passive antibody therapy.

The administration of the COVID-19 convalescent plasma must, however, fulfill some requirements related to availability of COVID-19 recovered donors: well-designed study protocols to guarantee the efficacy analysis of such an intervention; governmental and institutional compliance, and; laboratory support to perform serological and molecular assays, including the measurement of viral neutralization and immune response.¹¹ In addition, the connection between hospitals, blood centers and the plasma industry must follow flawless strategies, as plasma units may be frozen before distribution or be manufactured as concentrated COVID-19 immunoglobulin.

46. 5/1/2020 Pérez C, Marín-Lahoz J: Serosurveys and convalescent plasma in COVID-19. *EClinicalMedicine* 23 (2020) 100370.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7252163/pdf/main.pdf>

The current pandemic is not only overwhelming the health systems of the affected countries but also is killing thousands of other ways healthy adults. Convalescent plasma has been proposed [1] and approved to treat COVID-19 based on the experience acquired treating other viral diseases such as influenza, Ebola, and SARS [2]. It is considered a safe treatment (at least its side effects and contraindications are well known) and it has proven to be efficacious in several viral infections for more than a century. Currently, several countries and health institutions are trying to gather convalescent sera for either empirical treatment or clinical trials. Based on the WHO interim guidance developed for the 2014 Ebola outbreak [3], convalescent plasma has advantages over other proposed treatment: it requires low technology (and therefore it can be produced where required independent of pharmaceutical companies), it is low cost and its production is easily scalable as long as there are sufficient donors.

47. 5/26/2020 FDA update 5/1/2020:

<https://web.archive.org/web/20200526150255/https://www.fda.gov/media/136798/download>

48. 5/30/2020 Alsuliman T, Alasadi L, Alkharat B, Srour M, Alrstom A: A review of potential treatments to date in COVID-19 patients according to the stage of the disease. *Current Research in Translational Medicine* 68 (2020) 93 – 104.

<https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC7260520&blobtype=pdf>

Convalescent plasma The FDA has recently approved convalescent plasma for serious or immediately life-threatening COVID-19 infections under emergency Investigational New Drug Application (eINDs) [80]. Convalescent plasma has been previously studied during other epidemics including H1N1 influenza virus pandemic, SARS-CoV-1 epidemic, and the MERS-CoV epidemic. Recently, a preliminary case series of five intubated COVID-19 patients with ARDS showed promising results. These patients received 400 ml of convalescent plasma containing neutralizing SARS-CoV-2-specific antibody (IgG) from recovered COVID-19 donors. All patients had gradual clinical and radiological improvement within 3 days and four patients no longer required respiratory support by day 9, viral loads also became negative within 12 days after transfusion. Seven clinical trials are currently registered [7,38,81].

49. 7/17/2020 Wortham JM, Lee JT, Althomsons S, Latash J, Davidson A, Guerra K, Murray K, *et.al.*: Characteristics of persons who died with COVID-19.—United States, February 12 – May 18, 2020. *Morbidity and Mortality Weekly Report (MMWR)*, July 17, 2020; 69 (28): 923-929. <https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e1.htm> and complete .pdf file: <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6928e1-H.pdf>

50. 8/23/2020 FDA issued an EUA for convalescent plasma on August 23, 2020. Using the following website: <https://www.fda.gov/media/141477/download> yields the overwritten final version of December 28, 2021. Using the Wayback Machine of the *Internet Archive*, one can access the first capture of the original August 23, 2020 document captured digitally on September 1, 2020:

<https://web.archive.org/web/20200901002808/https://www.fda.gov/media/141477/download>

51. 8/23/2020 FDA News Release: FDA issues emergency use authorization for Convalescent Plasma as potential promising COVID-19 treatment, another achievement in Administration's fight against pandemic. U.S. Food & Drug Administration.

<https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients as part of the agency's ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its [decision memorandum](#), this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product.

Today's action follows the FDA's extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing. The EUA authorizes the distribution of COVID-19 convalescent plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with COVID-19.

Alex Azar, Health and Human Services Secretary:

"The FDA's emergency authorization for convalescent plasma is a milestone achievement in President Trump's efforts to save lives from COVID-19," said Secretary Azar. "The Trump Administration recognized the potential of convalescent plasma early on. Months ago, the FDA, BARDA, and private partners began work on making this product available across the country while continuing to evaluate data through clinical trials. Our work on convalescent plasma has delivered broader access to the product than is available in any other country and reached more than 70,000 American patients so far. We are deeply grateful to Americans who have already donated and encourage individuals who have recovered from COVID-19 to consider donating convalescent plasma."

Stephen M. Hahn, M.D., FDA Commissioner:

"I am committed to releasing safe and potentially helpful treatments for COVID-19 as quickly as possible in order to save lives. We're encouraged by the early promising data that we've seen about convalescent plasma. The data from studies conducted this year shows that plasma from patients who've recovered from COVID-19 has the potential to help treat those who are suffering from the effects of getting this terrible virus," said Dr. Hahn. "At the same time, we will continue to work with researchers to continue randomized clinical trials to study the safety and effectiveness of convalescent plasma in treating patients infected with the novel coronavirus."

Scientific Evidence on Convalescent Plasma

Based on an evaluation of the [EUA criteria](#) and the totality of the available scientific evidence, the FDA's Center for Biologics Evaluation and Research determined that the statutory criteria for issuing an EUA criteria were met.

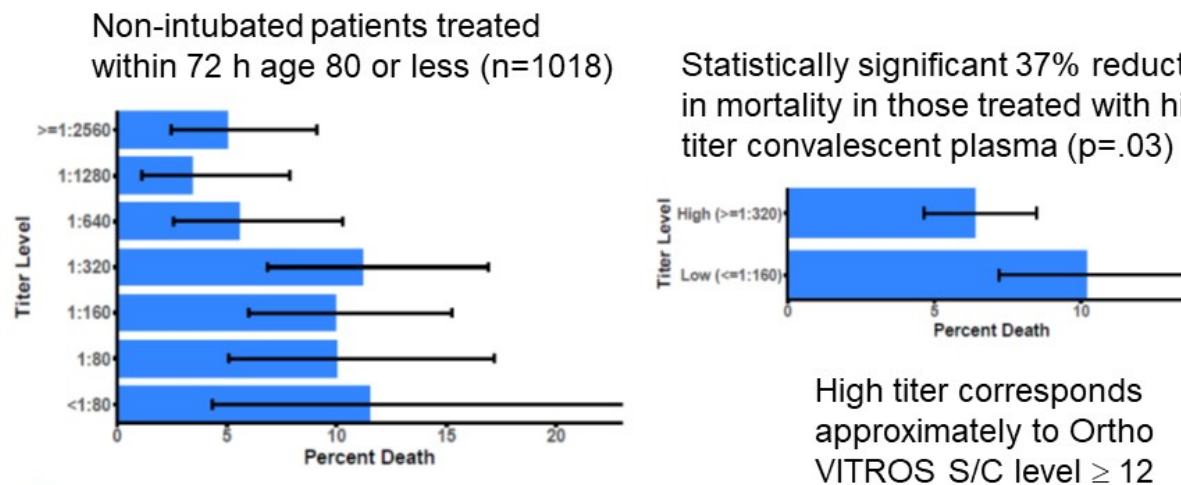
The FDA determined that it is reasonable to believe that COVID-19 convalescent plasma may be effective in lessening the severity or shortening the length of COVID-19 illness in some hospitalized patients. The agency also determined that the known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product and that there are no adequate, approved, and available alternative treatments.

The EUA is not intended to replace randomized clinical trials and facilitating the enrollment of patients into any of the ongoing randomized clinical trials is critically important for the definitive demonstration of safety and efficacy of COVID-19 convalescent plasma. The FDA continues to recommend that the designs of ongoing randomized clinical trials of COVID-19 convalescent plasma and other therapeutic agents remain unaltered, as COVID-19 convalescent plasma does not yet represent a new standard of care based on the current available evidence.

The EUA remains in effect until the termination of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19. The EUA
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COVID-19 Convalescent Plasma

Reduction in Death at 7 Days



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y be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

52. 8/23/2020 FDA Clinical memo

<https://web.archive.org/web/20200823215842/https://www.fda.gov/media/141480/download>

53. 8/23/2020 Hinton DM, FDA Chief Scientist: Letter to Dr. Kadlec regarding the EUA for COVID-19 Convalescent Plasma. FDA

54. 8/24/2020 Beachum L, Taylor A, Knowles H, Shammas B, Denham H, Kornfield, Thebault R: Scientists express doubts about coronavirus treatment touted as breakthrough by Trump. The Washington Post, August 24, 2020.

<https://www.washingtonpost.com/nation/2020/08/24/coronavirus-covid-live-updates-us/>
Unable to access this article today and substitute article by the Washington Post is truncated with the article being written by Antonia Noori Farzan. Unable to access full article via the Wayback Machine of the *Internet Archive*.

55. 8/24/2020 MacGinley L, Abutaleb Y, Bernstein L: Some Trump Administrative claims on effectiveness of convalescent plasma are wrong or dubious, scientists say. The Washington Post, August 24, 2020.

<https://www.washingtonpost.com/health/2020/08/24/some-administration-claims->

[effectiveness-convalescent-plasma-are-wrong-or-dubious-scientists-say/](https://web.archive.org/web/20200903024635/https://www.washingtonpost.com/health/2020/08/24/some-administration-claims-effectiveness-convalescent-plasma-are-wrong-or-dubious-scientists-say/) but able to access article via the Wayback Machine of the *Internet Archive*:

<https://web.archive.org/web/20200903024635/https://www.washingtonpost.com/health/2020/08/24/some-administration-claims-effectiveness-convalescent-plasma-are-wrong-or-dubious-scientists-say/>

56. 9/1/2020 NIH: Statement on COVID-19 treatment guidelines. (Accessible only through the *Internet Archive* as the NIH removed all 72 update versions ncluded the last publication of February 29, 2024) on August 16, 2024.

57. **** [For a review of the NIH COVID-19 Treatment Guidelines Panel: Perspectives and Lessons Learned one should read: Gulick RM, Pau AK, Daar E, Evans L, Gandhi RT, Tebas P, Ridzon R, Masur H, Lane HC, and the NIH COVID-19 Treatment Guidelines Panel. *Ann of Internal Medicine* 2024 Nov; 177: 1547-1559. https://www.acpjournals.org/doi/full/10.7326/ANNALS-24-00464?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org]*****

Continuation of reference 55.

<https://web.archive.org/web/20200901235858/https://www.covid19treatmentguidelines.nih.gov/statement-on-convalescent-plasma-eua/>

The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of Convalescent Plasma for the Treatment of COVID-19

Last Updated: September 1, 2020

On August 23, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA)* for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19.^{1,2} The COVID-19 Treatment Guidelines Panel (the Panel) reviewed the available evidence from published and unpublished data on convalescent plasma for the treatment for COVID-19, including the FDA analyses that supported the EUA.

There are currently no data from well-controlled, adequately powered randomized clinical trials that demonstrate the efficacy and safety of convalescent plasma for the treatment of COVID-19. The FDA analysis of data on a subset of hospitalized patients from the Mayo Clinic's Expanded Access Program (EAP) compared outcomes in patients who received convalescent plasma with high titers of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) neutralizing antibodies to outcomes in patients who received plasma with low titers and found no difference in 7-day survival overall. Among patients who were not intubated, 11% of those who received convalescent plasma with high antibody titers died within 7 days of transfusion compared with 14% of those who received convalescent plasma with low antibody titers. Among those who were intubated, there was no difference in 7-day survival. Although these data suggest that convalescent plasma with high antibody titers may be beneficial in nonintubated patients, uncertainty remains about the efficacy and safety of convalescent plasma due to the lack of a randomized control group and possible confounding in the Mayo Clinic's EAP. Additionally, antibody levels in currently available COVID-19 convalescent plasma are highly variable, and assays to determine the effective antibody titers remain limited.³

Based on the available evidence, the Panel has determined the following:

- There are insufficient data to recommend either for or against the use of convalescent plasma for the treatment of COVID-19.
- Available data suggest that serious adverse reactions following the administration of COVID-19 convalescent plasma are infrequent and consistent with the risks associated with plasma infusions for other indications. The long-term risks of treatment with COVID-19 convalescent plasma and whether its use attenuates the immune response to SARS-CoV-2, making patients more susceptible to reinfection, have not been evaluated.
- Convalescent plasma should not be considered standard of care for the treatment of patients with COVID-19.
- Prospective, well-controlled, adequately powered randomized trials are needed to determine whether convalescent plasma is effective and safe for the treatment of COVID-19. Members of the public and health care providers are encouraged to participate in these prospective clinical trials.
- The Panel will continue to evaluate emerging clinical data on the use of convalescent plasma for the treatment of COVID-19 and will update the [Convalescent Plasma](#) section of the Guidelines in the near future.

* The criteria for issuance of an EUA are not the same as the standards for FDA approval.⁴ There are currently no FDA-approved therapies for the treatment of COVID-19.

References

1. Food and Drug Administration. Coronavirus disease 2019 (COVID-19) EUA information. 2020. Available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>. Accessed August 31, 2020.
 2. Food and Drug Administration. Convalescent plasma letter of authorization. 2020. Available at: <https://www.fda.gov/media/141477/download>. Accessed August 31, 2020.
 3. Food and Drug Administration. EUA 26382: Emergency Use Authorization (EUA) Request. 2020. Available at: <https://www.fda.gov/media/141480/download>. Accessed August 31, 2020.
 4. Food and Drug Administration. Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders. January 2017; Available at: <https://www.fda.gov/media/97321/download>. Accessed August 31, 2020.
58. 2020-09-01 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. August 23, 2020 **Strict patient eligibility requirements when patients were severely ill were mandated.**
<https://web.archive.org/web/20200901081726/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma#Patient%20Eligibility>
59. 2020-09-02 01 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. September 2, 2020 **By 10 days later, patient eligibility requirements were removed.**
<https://web.archive.org/web/20201115054330/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>
60. 9/2/2020 FDA: Recommendations for Investigational COVID-19 Convalescent Plasma. <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma> yields last update of January 10, 2022. If one tries to access the September 2, 2020 version using above URL pasted into the Wayback Machine of the *Internet Archive*, the yield goes back to April 8, 2020, with 1,724 captures and thus one can find the version of this FDA document for 9/2/2020 that was captured on September 3, 2020: <https://web.archive.org/web/20200903052802/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>
61. 9/14/2020 Schneider G: In Kentucky visit, Dr. Deborah Birx says she has never “downplayed” Covid-19 risks. Louisville Courier Journal, September 14, 2020.
<https://www.courier-journal.com/story/news/2020/09/14/covid-19-task-force-dr-birx-have-never-downplayed-coronavirus/5791067002/>

The physician said her team also is asking university leaders to consider launching additional antibodies tests, which are blood proteins that can indicate whether students and university staff already have had the virus and may be candidates for donating convalescent plasma. Antibodies-rich plasma has been shown to help critically ill patients fight off the infection.

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9/14/2020 Schneider G: In Kentucky visit, Dr. Deborah Birx says she has never “downplayed” Covid-19 risks. Louisville Courier Journal, September 14, 2020. <https://www.courier-journal.com/story/news/2020/09/14/covid-19-task-force-dr-birx-have-never-downplayed-coronavirus/5791067002/>

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9/21/2020 FDA Withdrawl of guidance: <https://www.regulations.gov/document?D=FDA-2020-D-1825-0011>

9/21/2020 Investigational COVID-19 Convalescent Plasma: Guidance for Industry; Availability. <https://www.regulations.gov/document?D=FDA-2020-D-1825-0001>

9/21/2020 Investigational COVID-19 Convalescent Plasma: Guidance for Industry <https://www.regulations.gov/document?D=FDA-2020-D-1825-0002>
.PDF hyperlink: Investigational COVID-19 Convalescent Plasma—Guidance for Industry, Document issued on September 2, 2020 *.PDF hyperlink:* *.PDF hyperlink:* Investigational_COVID-19_Convalescent_Plasma_Guidance_for_Industry%20(3).pdf
also: <https://www.fda.gov/media/136798/download>

Fresh Frozen and COVID-19 Convalescent Plasma Numbers:

100 Whitaker BI, Rajbhandary S, Harris A: The 2013 AABB Blood Collection, Utilization, and Patient Blood Management Survey Report. American Association of Blood Banks, December 18, 2015. <http://www.aabb.org/research/hemovigilance/bloodsurvey/Documents/2013-AABB-Blood-Survey-Report.pdf>

101 Jones JM, Sapiano MRP, Savinkina AA, Haass KA, Baker ML, Henry RA, Berger JJ, Basavaraju SV: Slowing decline in blood collection and transfusion in the United States – 2017. Transfusion, March 2020; 60: S1 – S9.

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Some Pertinent Transcripts and Excerpts:

Transcript 1, Reference 78: Transcript of interview between Stephen Morrissey, PhD, the Managing Editor, and Jeffrey Drazen, M.D., the Editor-in-Chief, *The New England Journal of Medicine* regarding the sharing of data from clinical trials <https://www.nejm.org/doi/10.1056/NEJMdo002418/full/>

(Related Article: Rosenbaum L: Bridging the data-sharing divide – Seeing the devil in the details, not the other camp. *N Engl J Med* 2017 June 8; 376(23): 2201-2203. <https://www.nejm.org/doi/pdf/10.1056/NEJMp1704482>)

Dr. Morrissey: Debate has continued over the most appropriate and effective way for investigators to share data from clinical trials. To advance that conversation, *The New England Journal of Medicine* sponsored the Sprint data analysis challenge inviting individuals and groups to use data from the systolic blood pressure intervention trial, or Sprint, to identify new biologic or clinical findings. The challenge culminated in a data summit that brought together trialists, data scientists, and patients to discuss aligning incentives for sharing clinical trial data. I'm Stephen Morrissey, managing editor of *The New England Journal of Medicine*, and I'm talking with Dr. Jeffrey Drazen editor-in-chief of the Journal. Dr. Drazen, why did the Journal choose the Sprint trial for its data sharing challenge? What about the data, for the team behind that study, made it particularly appropriate for this kind of undertaking?

Dr. Drazen: The Sprint trial was sponsored by the United States National Institutes of Health, with the idea of changing the practice of treating systolic hypertension in people over 55 years of age. So, this was a trial done in the public domain with public money. It was a very important trial because it was stopped early because of effectiveness in the group that had the systolic blood pressure lowered to a target of 120 mm of mercury compared to the standard of 140 mm of mercury. One year after the trial was published, originally in November of 2015--that is, in November of 2016--the National Heart Lung and Blood Institute made the data available on a public website. We thought this was a good opportunity to give people who wanted to reexamine the data and to find new things in the data, an opportunity to do so and to challenge them to teach us something that we didn't know. This was all meant to illustrate the power of sharing clinical trial data to enhance our understanding of a clinical trial.

Dr. Morrissey: So, given that--what can the results of the Sprint challenge of the contest, the number and types of participants, and the content of the final submissions--What can those things tell us about how data sharing would work in the real world and what roadblocks might exist?

Dr. Drazen: So, we had 143 entries to the Sprint challenge. There were more people who started but, in order to enter the contest, you first had to show that you could master the data set by answering questions that showed that you understood the data structure and could extract from it the correct clinical information. So that narrowed the field a little, but then we were left with 143 people that examined the data set in many different ways. Some examined it to look for risk factors that would show that even though you lowered your systolic pressure and prevented cardiovascular events, there were other adverse consequences that may weigh against them--such as renal failure or other issues such as syncope. There were other people that looked at ways to predict who would do better or who would do worse based on initial conditions or the drugs that people were taking. Other people examined the data that came in during the trial and said that people who had a marked variability in their blood pressure over the course of the trial we're more likely to have a major adverse cardiovascular event than those who did not. So, putting the data out in the public domain allowed many people to examine different facets of it. The data are still there and you can look at that on our website and decide whether you think any of these really makes a difference in understanding how to treat systolic hypertension in people over 55 years of age. But I think that there's another really important issue that derives from these data. When 143 groups looked at the data, they found a few minor errors in the paper that we published--nothing that impacted on the conclusions; but all the groups agreed that the Sprint investigators in their article that they published in November of 2015 had it right that. That, in fact, patients that had lowered their systolic blood pressure to 120 target did better than 140. So, we think that it's really enhance the public's trust in the clinical trial when so many people could analyze the data and reaffirm the major conclusions.

Dr. Morrissey: The debate over the merits of data sharing has typically--it's been a heated discussion over the past year or so; but it's typically been seen in terms of clinical trialists versus data scientists. The journal summit also included patients who had participated in clinical trials. What did their perspective add to the conversation?

Dr. Drazen: The patients' perspective changed the conversation. People who listened to the people who had actually been in the Sprint trial, changed their thinking about it. One of the participants in the meeting wrote me after the meeting and said that they had originally sided with the clinical trialists in that they thought the data didn't need to be shared with anyone; but, after hearing from the patients, this person said: You know, I see their point of view. We really need to include the patients in our thinking when we design the trial, when we report the trial, and when we share the data with others. So, since people have put themselves at risk to be in these trials and to give us the information that we need so that we can stand at the bedside or in our offices and tell patients we know what we're doing because we've studied it, we really need to listen to their voice; and their voice was clear: Share our data responsibly.

Dr. Morrissey: One topic that came up during the summit was the ownership of the data. What would it look like for patients to have true control and ownership over data from clinical trials, and is that even feasible?

Dr. Drazen: It's a very difficult question because we're not quite sure what you mean by ownership. An individual patient certainly deserves to understand how he or she fared in the trial. For example, if it was a blinded placebo-controlled trial, whether they received the active or the control treatment. But, in order to analyze the data, you need to be able to see all of the data, and not just that individual patient data, and you need to be able to analyze it from the perspective of the question that the trial was posed to ask.—And, we think that sharing with the patients the ability to ask the question, to frame the question, is really key. So, they begin to participate in the process of asking the question that we're using the clinical trial to answer; and then they become part of the answer, and there isn't a fight over who owns the data but rather we can all use it together to advance human health.

Dr. Morrissey: In a recent editorial, you and other members of the international committee of medical journal editors, the ICMJE, layout new requirements for clinical trials and data sharing. Can you tell us about that policy and when it will go into effect?

Dr. Drazen: The International Committee of Medical Journal Editors have decided that when an article is published, there needs to be a data sharing plan that is filed with the article. You need to tell people what data are you going to share; with whom, when, and by what means; and for what purpose. So, for example, if in the Sprint trial the investigators could have said that at one year's time, they would share the data that underlay the paper that was being published in the *New England Journal of Medicine* with qualified investigators for the purpose of examining the data set to see if there were subgroups in it that may change the way we would think about treating systolic hypertension in older Americans. But the key point is that the data sharing plan is in the public domain. So, when the article is published, the investigators make a commitment as to what data they plan to share, with whom, when, and by what means. That will go into effect on July 1st, 2018, when an article is submitted for publication. Six months later, on January 1st, 2019, when a new clinical trial is started, the investigators will need to file a data sharing statement where they state what data will be available as the trial progresses and when it ends--again with whom, by what means, and for what purpose; and the idea is to put on the public record how the data will be shared. Now the data sharing statement can be modified over time as the investigators accrue data or accrue results; but, when an article is published from the clinical trial, we'll then have a data sharing plan that will go with the article so we perceive that there will be two different entities closely related.

Dr. Morrissey: Finally, how will these new ICMJE requirements move us closer to the ultimate goal--mandating universal data sharing? What's the road ahead?

Dr. Drazen: We actually don't think that there will need to be a mandate for universal data sharing. We think there'll be a desire for universal data sharing. That, by putting the information in the public domain, investigators will see that this is a partnership with patients willing to put themselves at risk and data

analysts gathering information to advance human health; and, therefore, it will make sense to do this and that we won't have to twist anyone's arm. Rather, we'll be doing it openly and willingly because everyone will see the advantages of gathering data and sharing data in a way that makes sense from the beginning other than it's an afterthought.

Dr. Morrissey: Thank you, Doctor Drazen.

Transcript 2, reference 24:

1. Marston HD, Paules C, Fauci AS: Monoclonal antibodies for emerging infectious diseases – Borrowing from history. N Engl J Med 2018 Apr 19; 378 (16): 1469 – 1472. https://www.nejm.org/doi/10.1056/NEJMp1802256?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed
2. Morrissey S, Fauci AS: Interview with Dr. Anthony Fauci on the use of monoclonal antibodies in the context of emerging infectious diseases. N Engl J Med 2018; 378. <https://www.nejm.org/doi/10.1056/NEJMdo002465/full/> [Transcript 2]

The hyperlink for the 2018 NEJM Morrissey interview of Dr. Fauci is:

<https://www.nejm.org/action/showMediaPlayer?doi=10.1056%2FNEJMdo002465&aid=10.1056%2FNEJMp1802256&area=>

Dr. Morrissey:

Although there is a long history of plasma derived treatments for several pathogens, only a handful of antibody therapies have been licensed for infectious diseases. But recent advances in the development of monoclonal antibodies could have important implications for our response to infectious disease outbreaks. I'm Stephen Morrissey, Managing Editor of the New England Journal of Medicine, and I am talking with Anthony Fauci, Director of the National Institute of Allergy and Infectious diseases. Dr. Fauci has coauthored a prospective article about the promise of monoclonal antibodies for rapid intervention during infectious disease outbreaks. Dr. Fauci: What are the primary benefits of using monoclonal antibodies for prevention and treatment infectious diseases? What advantages do they have over current approaches?

Dr. Fauci:

Well, one of the things that got us to be very interested in that is just that potential advantage. Namely, that when you have to respond, for example, to an unexpected outbreak of an infectious disease, one of the major tools against that to control it or hopefully eliminate it is development of a safe and effective vaccine. The problem with that is that the time that it takes, even when you put it on a rapid pace, the time that it takes to get a vaccine that you show to be safe and effective often falls behind and lags dramatically behind the actual outbreak itself. Whereas if you can with our techniques that we have right now which of greatly improved over the past several years to isolate and develop monoclonal antibody specific to the agent in question--you can use it much more rapidly. Obviously there's the issue of being able to scale up, but you get a monoclonal antibody in hand soon after you're confronted with an outbreak has a major advantage over the long time-honored but nonetheless rather drawn out process of developing a vaccine.

Dr. Morrissey:

You write in your article that several antibody therapies have been licensed for infectious diseases. What have researchers learned from the development of those therapies and for more recent attempts to create monoclonal antibodies against—say-- Ebola or Zika?

Dr. Fauci:

Well, for example, a classic monoclonal antibody for prophylaxis against Respiratory Syncytial Virus has been developed with considerable success. We began thinking very intensively about this just literally over the past few years when we in rapid succession had to confront both the Ebola outbreak followed by the Zika outbreak. And it became very clear that during the Ebola outbreak that there were monoclonal antibodies in the form of ZMapp that was able to actually have an impact even though we did not have the opportunity of doing a very large clinical trial. We did show that there was clearly a tendency towards a benefit of this cocktail of three mouse human chimeric antibodies against Ebola, that we felt that this particular approach if perfected both in the development and scale-up of these antibodies might have an important role in future outbreaks. So, we're thinking that this is going to be something, and including for example influenza, so there have been now a couple of monoclonal antibodies that have been made against

influenza. And when you think in terms of a threat of a pandemic influenza and you would want to get an antibody that would be effective in neutralizing a brand new virus well before the time it takes to develop the vaccine, here again is something that we're going to be pursuing and are pursuing at the present time.

Dr. Morrissey:

So how do you envision that process of developing new antibody therapies during an outbreak?

Dr. Fauci:

There are a couple of ways of doing that. Probably the easiest way, because the technology now is so sophisticated, is to get an individual who has been infected with whatever pathogen is the one behind the outbreak. And because of the ability now to clone the B cells from the B cell repertoire and essentially fish out—and, truly metaphorically fishing-out the right B cell clones that have the specificity that you are thinking about and wanting to develop and immediately get those to be cloned, sequenced, and then the development of a high through-put process to give you monoclonal antibodies. That's something that was unheard of years ago—literally unheard of where you can actually probe and interrogate the B cell repertoire and the B cell lineage of a person who has recovered from the infection in question; and use those B cells as the source of the monoclonal antibody in question. And that's something that could be done immediately, and from the standpoint of the process of it, to be done very rapidly. So you can envision an outbreak where you have right-away, the sentinel people you have clearly getting sick from the pathogen you have in question and as they recover you just draw some blood from them and you can pull out with the techniques we have a variety of B cell clones that have various specificities and then you can test in vitro what is the best, what has the highest affinity, what is the most specific, what are the epitopes involved, and then start using them for both diagnosis, prophylaxis, and for treatment.

Dr. Morrissey:

You talk in your article about the current high cost of production and complexity of administration of these monoclonal antibodies. So how great a limitation is that and do you foresee a time when those issues will be less of a barrier than they are now?

Dr. Fauci:

Well, that's a great question, and I'd have to answer totally, honestly—that it is a barrier that is substantial right now at present. But as we've done with so many other things that we've been able, we in the field, not me personally, but we in the field have been able to develop over years—is that once you get the first step namely the specificity, the effectiveness of a particular antibody, then you work on the development of scale-up. But the idea of scaling up at a reasonable cost where these antibodies can be used widely is a challenge. But I do believe that as we get better and better at it as we have with other technologies that have started off to be very cumbersome and very expensive, I believe over time when there is accelerated interest in this approach which I believe there will be that we will be able to overcome that barrier of the ability to produce at a high degree.

Dr. Morrissey:

In your article, you describe three indications for monoclonal antibodies: the treatment of infected individuals, targeted prophylaxis to protect high-risk individuals, and targeted prophylaxis to interrupt transmission in populations at average risk. So which of these strategies do you think has the most potential to halt the spread of an epidemic?

Dr. Fauci:

Well, clearly if you are talking about halting the spread of an epidemic, the last two that you mentioned because the first one is the treatment of an infected individual. Now obviously you can say well treatment will turn out to be prevention because if you treat a particular person they may not transmit it to another; but I think the much more efficient way of preventing the expansion of an outbreak is the targeted prophylaxis either directly at high risk individuals or even at a population level to prophylaxis and interrupt transmission in people who are at average risk and that is really what we talk about in interrupting the chain of transmission. So, if you have an influenza outbreak, you may be able to use this as prophylaxis before you get a vaccine that is available to essentially have a more population-

based prevention. So, I believe the high risk individuals that are targeted for prophylaxis is going to be a very important way to interrupt certain outbreaks regardless of what the source of that outbreak is.

Dr. Morrissey:

Finally, what will it take to increase our interest in our investment in the use of monoclonal antibodies for infectious diseases? What, for example, is NIAID doing?

Dr. Fauci:

Let me answer your question broadly, then I will get back to the specific of what we are doing. Really nothing succeeds like success as they say. Once you start demonstrating the effectiveness of this approach in different outbreaks—and we have seen inklings of this with the ZMapp approach to Ebola with some of the monoclonal antibodies—all-be-it in the animal models with Zika, they worked very well in the animal models to prevent the transmission of the virus to a fetus in an animal model; and thus prevented the congenital defects in this animal model. I believe that when we get to the point of testing it in humans, under these circumstances, we will see similar success. So, that is what I mean by nothing succeeds like success once you have a few examples of successful application of this particular approach. You are going to get a lot more interest in it. What we at NIH are doing is what we do most of the time is these types of approaches; and that is, to do the basic and clinical research to get this developmental process to be quick and to be effective. We done that and it ranges all the way from the fundamental basic research on B cell lineage--that really led to the ability to develop monoclonal antibodies at a high degrees of specificity and the high degree of ability to neutralize whatever a particular pathogen you have in question. So, the NIH 's job will be what we have been doing all a long, is the fundamental basis to give clinical research leading to the application of these types of interventions.

Dr. Morrissey:

Thank you, Dr. Fauci.

Transcript 3, Reference 16, Annotated Bibliography 336:

2020-03-05. YouTube: Regeneron's Leonard S. Schleifer meets with Trump at the White House, 3/2/2020. https://www.youtube.com/watch?v=31i6p_stzW8 AT THIS MEETING, PRESIDENT TRUMP AND ALL THE PEOPLE OF THE WORLD WERE MISLED BY OMISSION / MISREPRESENTING THE DISTINCTION BETWEEN *ACTIVE IMMUNIZATION (vaccines)* versus *PASSIVE IMMUNIZATION (convalescent plasma, convalescent sera, monoclonal antibodies, monoclonal antibody cocktail, etc.)*.

The cost of production of a dose (1/2 unit of fresh frozen plasma) COVID-19 Convalescent Plasma (CCP) which was available in March 2020 is ~\$200 while a dose of REGEN-COV™ (Casirivimab with imdevimab) which would be several months into the future and would cost ~\$3000 a dose. A monoclonal antibody is specific for one antigen (e.g. a specific site on the spike point) and is likely to be ineffective on future variants like Omicron. Polyclonal antibodies like Convalescent Plasma will have multiple antibodies of such sites as on the spike protein and will be available as the SARS-CoV-2 mutates. (e.g. more effective on the Omicron variant).

***** Full 56:54 minute meeting in *The White House* where they went around the table introducing the key players: <https://www.c-span.org/video/?469926-1/president-trump-meeting-pharmaceutical-executives-coronavirus> with the complete transcript: <https://web.archive.org/web/20200303160403/https://www.whitehouse.gov/briefings-statements/remarks-president-trump-members-coronavirus-task-force-meeting-pharmaceutical-companies/> This linchpin *White House* meeting included CEOs, presidents, and Medical Directors of the major biomedical and pharmaceutical companies who could provide vaccines, monoclonal antibodies, and antivirals; the Secretary of the U.S. Department of Health and Human Services and its agencies (e.g.: FDA, NIH, CDC, etc.); and the Vice-president and the President of the United States of American. 1.) Nobody defined the foundational basics of Clinical Immunology: Active Immunization and Passive Immunization. 2.) Everything was in Generalities – NOT THE INDIVIDUAL PATIENT! 3.) The not-for-profit American Red Cross was NOT officially invited “to the table” until July 30, 2020—by that time, the U.S.A. had gone so far down the Rabbit Hole, they did not know how to get out! 4.) No physician in that room, on that day, has probably cared for the individual patient since Medical School.

Individuals at the White House meeting of March 2, 2020.

President Donald Trump, 2 years Fordham University and the 2 years Wharton School of the University of Pennsylvania, B.S. in Economics

Alexander Azar, Secretary of the U.S. Department of Health and Human Services, summa cum laude in government and economics from Dartmouth and J.D. from Yale University

Emma Walmsley, CEO of GlaxoSmithKline, MA in Classics and Modern Languages from Oxford University (Christ Church)

Anthony Fauci, M.D., Director of the NIAID of the NIH, College of the Holy Cross with a BA in classics and a MD from Cornell University graduating 1st in his class

Robert Redfield, M.D., Director of the CDC, graduated from Georgetown University's College of Arts and Sciences with a BS and MD from Georgetown University School of Medicine

Daniel Menichella, CEO of CureVac, BA in economics from Harvard University and a MBA from University of North Carolina at Chapel Hill

John Shiver, PhD, Senior Vice President, Vaccines Global R&D at Sanofi Vaccines, BS in Chemistry/Mathematics, Woffard College and a PhD in Chemistry from the University of Florida

Leonard Schleifer, M.D., PhD, CEO Regeneron, BS at Cornell University and an MD-PhD from the University of Virginia

Stephane Bancel, CEO of Moderna, masters degrees from both CentraleSupélec of Paris-Saclay University (engineering) and the University of Minnesota (biological engineering) and an MBA from Harvard Business School

Daniel O'Day, BS, MBA, Chairman and CEO of Gilead Sciences has a BS in biology from Georgetown University and an MBA from Columbia University in New York

Steven Hahn, M.D., Commissioner, U.S. Food and Drug Administration, BA in Biology from Rice University and MD from Temple University

Mikael Dolsten, M.D., Ph.D., Chief Scientific Officer of Pfizer, Ph.D. in tumor immunology and a MD from Lund University

Joseph Kim, Ph.D., Inovio Pharmaceuticals, BS degrees in Chemical Engineering and Economics from MIT, a Ph.D. in immunology from the University of Pennsylvania, and an MBA in finance from the Wharton School of Business, University of Pennsylvania

Paul Stoffels, M.D., Chief Scientific Officer of Johnson & Johnson, studied medicine at the University of Diepenbeek and the University of Antwerp in Belgium and Infectious Diseases and Tropical Medicine at the Institute of Tropical Medicine in Antwerp, Belgium.

Anne Schuchat, M.D., Principal Deputy Director of the CDC, Swarthmore College and MD Dartmouth Medical School

Stanley Erck, President and CEO of Novavax, undergraduate degree from the University of Illinois and MBA in economics and finance from the Booth School of Business, The University of Chicago

Ambassador Deborah Birx, M.D., U.S. Department of State, BS in chemistry from Houghton College and MD from Pennsylvania State University.

Below is the excerpted transcript of President Trump's and Dr. Leonard S. Schleifer's interaction of March 2, 2020, in the Cabinet Room of *The White House*. Dr. Schleifer's euphemistic response to President Trump question: "... *Passive Vaccination*..." was an incorrect, misleading, obfuscative merger of two mutually-exclusive, fundamental, immunologic clinical principles that would misdirect and confused U.S. Medicine in the Treatment (not Prophylaxis) of COVID-19 from March 2, 2020 to this very day. In epidemiological terms, that articulation of the euphemistic phrase, *Passive Vaccination*, and the Meeting in *The White House* of March 2, 2020, became the INDEX MOMENT that resulted in the overall misdirection of U.S. Medicine's overall addressing of the early treatment (within 72 hours) of all individual SARS-CoV-2-infected patients with COVID-19 Convalescent Plasma (CCP), subsequently monoclonal antibodies, and the antiviral, Remdesivir:

President Trump: Lenny?

Leonard S. Schleifer, M.D., Ph.D.: Thank you, Mr. President, for having us. Len Schleifer, the founding CEO of Regeneron, a company that I built with George Yancopoulos over the last 30 years. And we are a monoclonal antibody primarily centered company. We are no strangers to the collaboration with the administration. We worked with Secretary Azar's group, BARDA, and we came up with a cure for Ebola.-And we're very proud of that. Dr. Fauci's group was really instrumental in testing that under unbelievable conditions in the Congo. It did not created quite as much excitement because, thank goodness, it didn't hit our shores.

But we can use the exact same technology, and we already have. We have 1,000 antibodies that are already sitting in dishes. We're screening them, selecting them, and we anticipate, if all goes well, 200,000 doses per month coming out of our factory in New York starting in August. The unique thing about our technology...

President Trump: That means you'd be able to use the vaccine that early?

Leonard S. Schleifer, M.D., Ph.D.: It depends on what we see; how we work closely with the FDA--which we will do. The FDA has already reached out to us but we've got to work closely...

President Trump: So that process would be faster than John's?

Leonard S. Schleifer, M.D., Ph.D.: It would be.

Secretary Azar: Can you explain why that would be?

Leonard S. Schleifer, M.D., Ph.D.: Well, so we make passive vaccines and therapeutics. Our drug will be able to protect you. Whether or not you're infected, it'll protect you from getting infected, or if you are infected, it would treat you. And the... we have just taken processes that normally take years, literally years, and we put them end to end, and now through them in weeks to months, that nobody else can do. So we're very excited to collaborate once again.

President Trump: So this would be a combination of the vaccine and also it will put it in a different way make you better, quicker.

Leonard S. Schleifer, M.D., Ph.D.: It will...think of it this way, if you, if you get immunized with one of these vaccines, you're going to make some antibodies to protect you. We're gonna already make those antibodies and give them to you--so you don't have to go through that whole process. So, to protect you and, as we showed this with the Ebola, you're given enough of them, it was life saving...life...truly life saving.

President Trump: That's true.

Leonard S. Schleifer, M.D., Ph.D.: ...beat out the antivirals. It really was the way to go. It's very predictable.

I just want to say I hope everybody succeeds here. I mean, this is bringing everybody together here is really critical and there's going to be success. This industry is really talented as an industry. Sometimes we run astray, but we're going to get this done.

President Trump: Thank you very much. Thanks, I appreciate it.

Transcript 4, Reference 486 from annotated bibliography:

486) 2020-06-08 Abbasi J: Anthony Fauci, MD, on COVID-19, Schools, and Larry Kramer. JAMA.com. JAMA 2020;324(3): 220-222
<https://jamanetwork.com/journals/jama/fullarticle/2767208>

Dr. FAUCI: Right now we have a major push on a program to develop monoclonal antibodies, convalescent plasma, and hyperimmune globulin, all of which are founded on the same principle of using an antibody that is directed against the virus for either prophylaxis or treatment. And I think you're going to see it's going to be both. We'd like to have available for those who are at risk—elderly and those with underlying conditions—either monoclonal antibodies or convalescent plasma. That's a very, very high priority.

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Dr Bauchner: Your equanimity, does it come from your parents? Does it come from your Jesuit education? It's extraordinary under the face of remarkable criticism, almost always unfair.

Dr Fauci: I think it does come a lot from my parents. My father was very much of a tolerant person who would accept people for what they are and very rarely ever criticized anybody. I went to a Jesuit high school in Manhattan, and from there I went to a Jesuit college. I think it was just right for me because I had always been interested in public service and not being somebody that ever attacks anybody, that accepts them for who they are and what they are. So it was kind of the perfect atmosphere to me to be educated in, and I just carried it along with me.

Feuerherd P: Dr. Fauci is dedicated to public service, formed at Jesuit high school. Catholic Review—Inspiring the Archdiocese of Baltimore. 2020 March 30. <https://catholicreview.org/dr-fauci-is-dedicated-to-public-service-formed-at-jesuit-high-school/>

Transcript 5, Reference 495 from Annotated Bibliography

495) 2020-06-19 McEnany K: White House Press Conference, June 19, 2020.

<https://www.youtube.com/watch?v=GxX6CgI7RJ4>

...Finally, well second, to finally, we are encouraged that we continue to gather positive data on a number of therapeutics: heparin; dexamethasone or steroids as it's more commonly known; convalescent plasma; and Remdesivir have all shown promise in treating coronavirus. Preliminary findings in a large UK-based recovery trial found that when steroids were used there was a 30% reduction in death for coronavirus patients on ventilators. The FDA is reviewing this recovery trial data now. Additionally, on convalescent plasma there's more encouraging news in partnership with Mayo Clinic. The Trump administration move very quickly on this therapy and it's earliest days recognizing that it showed promise. Through the FDA Mayo Clinic and the administration's work in our hand-in-hand partnership, we found that this treatment is very promising--this has shown that the administration has left no stone unturned in looking at every possible treatment at the very early stages. The lead investigator of this Mayo Clinic study, Dr. Michael Joyner, summed up his work in saying that convalescent plasma "continues to look promising" noting the "excellent news of this study which covered a diverse population of patients about 20% were African-American, nearly 35% Hispanic, 5% Asian, and 40% women. Prior experience with respiratory viruses and some data that have emerged globally suggest convalescent plasma has the potential to lessen the severity or shorten the length of the illness caused by COVID-19. The results from the Mayo underscore that promise. As you can see, the Trump administration and FDA led on identifying convalescent plasma as a therapeutic and the results are encouraging...

Transcript 6, The official transcript of *The White House* Press Conference of August 23, 2020, from *The White House* can be found at:

<https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-press-briefing-august-23-2020/>

Trump D: Donald Trump August 23 White House COVID-19 Press Conference Transcript. Rev Aug 23, 2020, 5:30 p.m. EDT. Video of the conference:

<https://www.youtube.com/watch?v=nE0EkrEICRk> Transcript:

<https://www.rev.com/blog/transcripts/donald-trump-august-23-white-house-covid-19-press-conference-transcript>

(The video of the August 23, 2020 White House press conference in its entirety:
<https://www.youtube.com/watch?v=nE0EkrEICRk>)

Transcript of August 23, 2020 White House press conference in its entirety:
<https://www.rev.com/blog/transcripts/donald-trump-august-23-white-house-covid-19-press-conference-transcript> This URL cannot be located at present but it was captured by the *Internet Archive* on September 1, 2020 and is copied verbatim from that *Internet Archive* URL:

Aug 23, 2020

Donald Trump August 23 White House COVID-19 Press Conference Transcript



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President Donald Trump held an August 23 coronavirus press conference where he announced the FDA is issuing an emergency authorization for a COVID-19 treatment called convalescent plasma. Trump touted the approval as a “historic announcement.” Read the full transcript of the press conference [here](#).

Donald Trump: (01:38)

Thank you very much, and it's good to see you all. Hope you had a great weekend at your convention. We're going to have a great convention coming up, and I look forward to it.

Donald Trump: (01:51)

But before I discuss a very historic breakthrough in our fight against the China virus, I'd like to provide an update on the recent wildfires in California and the storms in the Gulf of Mexico. Yesterday, I approved a major disaster declaration for California, spoke to Governor Newsom as they battled two of the worst wildfires in the history of their state. That continues.

Donald Trump: (02:19)

The federal government has already deployed over 26,000 first responders and personnel to battle the wildfires. We're working very closely with the Governor and very closely with a lot of great state representatives and local representatives. We'll take care of the situation, but we have 26,000 first responders already. Our hearts go out to the thousands of families who have lost their homes, as we grieve for the families of two first responders and five residents who have tragically lost their lives in a very horrific fire, one of the biggest we've ever seen.

Donald Trump: (03:01)

My administration is also closely monitoring Hurricane Marco and Tropical Storm Laura, which are coming in rapidly. Hurricane Marco is expected to make landfall in Louisiana tomorrow, and Tropical Storm Laura is expected to hit Louisiana two days later. This is somewhat unprecedented, the scope of the storms, and also the fact that they come so quickly after one another. Both storms have the potential of gathering strength before they make landfall and could cause significant damage across the Gulf Coast and also in Puerto Rico. We have everybody stationed and ready to go in Puerto Rico and the Gulf Coast. We have tremendous, tremendous people. FEMA is lined up. We have the Coast Guard ready. The Coast Guard has done a fantastic job. They do such good work, and we want to thank our great Coast Guard.

Donald Trump: (03:58)

I'm asking all Americans in the storm's path to follow the instructions of your state and local governments very closely. I've approved emergency declarations for Puerto Rico and for Louisiana. FEMA is mobilized on the ground and is ready to help. They will be in there very quickly, very, very quickly. I spoke to Governor John Bel Edwards also of Louisiana, and I've informed him, and at his request also, a major disaster declaration is signed and ready to go. We have everybody ready in Puerto Rico, the Gulf Coast, Louisiana, and also on the forest fires in California. We have a great team. Unfortunately, we have some very, very powerful natural disasters.

Donald Trump: (04:47)

On the therapeutics front, this is what I've been looking to do for a long time. This is a great thing. Today, I'm pleased to make a truly historic announcement in our battle against the China virus that will save countless lives. The FDA has issued an Emergency Use Authorization, and that's such a powerful term, Emergency Use Authorization, for a treatment known as convalescent plasma. This is a powerful therapy that transfuses very, very strong antibodies from the blood of recovered patients to help treat patients battling a current infection. It's had an incredible rate of success. Today's action will dramatically expand access to this treatment.

Donald Trump: (05:39)

I want to thank Dr. Hahn and Secretary Azar. I want to thank the FDA, all of the people that have been working very hard on this. It showed tremendous potential. It's only made possible because of Operation Warp Speed. That is everybody working together. We're years ahead of approvals that we would be if we went by the speed levels of past administration. We'd be two years, three years behind where we are today, and that includes on vaccines that you'll be hearing about very soon, very shortly.

Donald Trump: (06:16)

To deliver treatments and vaccine to save lives, we're removing unnecessary barriers and delays, not by cutting corners, but by marshaling the full power of the federal government. We provided \$48 million to fund the Mayo Clinic study that tested the efficacy of convalescent plasma for patients with the virus. Through this study over 100,000 Americans have already enrolled to receive this treatment,

and it is proven to reduce mortality by 35%. It's a tremendous number. The FDA, MIT, Harvard, and Mount Sinai Hospital have also found convalescent plasma to be a very effective method of fighting this horrible disease. Based on the science and the data, the FDA has made the independent determination that the treatment is safe and very effective.

Donald Trump: (07:12)

Recently, we provided up to \$270 million to the American Red Cross and America's blood centers to support the collection of up to 360,000 units of plasma. In late July, we launched a nationwide campaign to ask patients who have recovered, and these are patients that have been incredible the way they've donated. But these are people recovered from the virus to donate plasma. Since then, weekly plasma donations have doubled. Today, I once again urge all Americans who have recovered from the virus to go to coronavirus.gov and sign up and donate plasma today, please. It's been really an incredible ... Just incredible people. The country has united so strongly behind this.

Donald Trump: (08:08)

I'll go over the numbers, but if you look at what's happened and the success that we've had that people don't talk about, the United States has experienced the lowest case fatality rate of any major country in the world. You don't hear that. The European Union's case fatality rate is estimated to be three times higher than that in the United States. Europe has seen 33% more fatalities compared to a typical non-pandemic year than the United States.

Donald Trump: (08:38)

I just want to ask two of our people that have done such a fantastic job, Alex Azar and Stephen Hahn to say a few words. Stephen, I want to thank you because the FDA really stepped up and especially over the last few days in getting this done. The results have been incredible, and I think you'll see the results even go up very substantially. So we appreciate it. And maybe I'll ask Alex to go first, and then Stephen. Thank you very much, Alex.

Alex Azar: (09:06)

Well, thank you very much, Mr. President. Thanks for the bold leadership that allowed us to deliver this very happy news today. Thanks to your all-of-America approach, America has done more than any other country to expand the arsenal that we have to battle COVID-19. Thanks to early efforts by your administration, Americans have broader access to these treatments, including convalescent plasma, than patients anywhere else in the world.

Alex Azar: (09:33)

In early April, early in our fight against COVID-19, the FDA, BARDA, the Mayo Clinic, and other partners sprang into action to set up an expanded access protocol for this promising treatment. President Trump is the right-to-try President, and he's fought hard to ensure that Americans can have access to promising COVID-19 treatments. Convalescent plasma has been a tried-and-true therapeutic method in prior outbreaks, but the President wanted to ensure that we develop the data to support its use. This FDA authorization is one result of that effort.

Alex Azar: (10:06)

The data we gathered suggests that patients who were treated early in their disease course, within three days of being diagnosed with plasma containing high levels of antibodies, benefited the most from treatment. We saw about a 35% better survival in the patients who benefited most from the treatment, which were patients under 80, who were not on artificial respiration. I just want to emphasize this point because I don't want you to gloss over this number. We dream in drug development of something like a 35% mortality reduction. This is a major advance in the treatment of patients. This is a major advance.

Alex Azar: (10:51)

Convalescent plasma is one new tool that we've added to our arsenal against COVID-19 alongside remdesivir, steroids, and a number of other promising options currently being studied. Because of the President's Operation Warp Speed, we expect to have other new results and new options reaching patients as soon as this fall. Operation Warp Speed is supporting experimental therapeutics all the way through to manufacturing, so that if they meet FDA's gold standard for safety and efficacy, they can begin reaching patients without a day wasted.

Alex Azar: (11:24)

Americans who have tested positive for and recovered from COVID-19 can go to coronavirus.gov to find out a quick, convenient way to play a potentially lifesaving role in our fight. Know if you donate plasma, you could save a life. We've also provided guidance, so healthcare providers can contact patients who have recovered from COVID-19 and give them information on how they can donate.

Alex Azar: (11:48)

So thank you again, Mr. President for supporting this remarkable progress against COVID-19, and I want to thank Dr. Hahn, Dr. Marks, and the entire team at the FDA for the speed with which they've approached this, the diligence to ensure that this meets the standards at FDA. I'll turn it over to Dr. Hahn, if it's okay, Mr. President.

Donald Trump: (12:07)

[crosstalk 00:12:07] thank you very much. Please, Doctor?

Dr. Hahn: (12:09)

Thank you, Mr. President-

Donald Trump: (12:10)

[crosstalk 00:12:10].

Dr. Hahn: (12:10)

... for your leadership. It's good to be here today to announce FDA's recent decision. From the beginning of this pandemic, the President has asked FDA to cut back red tape to try to speed medical products into the hands of providers, patients, and American consumers. I just want to echo the President's thanks to the more than the 17,000 men and women who work at FDA. They have worked day and night to, in fact, do that.

Dr. Hahn: (12:36)

Plasma is the liquid portion of the blood. That liquid portion contains the natural immunity that someone develops in response to an infection, in this case COVID-19. That liquid portion can be extracted. And for many years, as the President and Secretary Azar said, has been given to patients with infectious diseases for more than a hundred years. So there was a really good rationale for why this might work. In fact, as was mentioned, in early April, an expanded access program was started at the Mayo Clinic with the support of the federal government under President Trump's leadership. That has gone on for the last four months. More than 90,000, close to 100,000, Americans have enrolled in this program, and over 70,000 have received treatment. This is one of the largest expanded access programs in the history of FDA. So a very successful approach to evaluating how convalescent plasma would work.

Dr. Hahn: (13:34)

In the independent judgment of experts and expert scientists at FDA who have reviewed the totality of data, not just the data from this expanded access program, but more than a dozen published studies, as well as the historical experience associated with this, those scientists have concluded that COVID-19 convalescent plasma is safe and shows promising efficacy, thereby meeting the criteria for an emergency use authorization. In the optimal patients, as described by secretary Azar, treated with convalescent plasma at the highest titers, there was a 35% improvement in survival, which is a significant clinical benefit. Now, we're waiting for more data. We're going to continue to gather data, but this clearly meets the criteria that we've established for emergency use authorization, and we're very pleased with these results.

Dr. Hahn: (14:27)

Let me just put this in perspective. Many of you know I was a cancer doctor before I became FDA commissioner, and a 35% improvement in survival is a pretty substantial clinical benefit. What that means is, and if the data continue to pan out, 100 people who are sick with COVID-19, 35 would have been saved because of the administration of plasma. We've seen a great deal of demand for this from doctors around the country. What this emergency use authorization today does, it allows us to continue that and meet the demand.

Dr. Hahn: (15:00)

Again, I want to echo the President's and the Secretary's ask of the American people. If you've recovered from COVID-19, please donate. It could save a life. Mr. President, thank you again.

Donald Trump: (15:11)

Thank you very much, Stephen. I appreciate it.

Speaker 6: (15:18)

Mr. President?

Donald Trump: (15:19)

Okay, any questions?

Speaker 6: (15:19)

Mr. President? Mr. President?

Speaker 7: (15:19)

Thank you, Mr. President. I want to first ask you about the COVID-19 drugs that are in phase three.

Donald Trump: (15:23)

[crosstalk 00:15:24].

Speaker 7: (15:24)

Are they going to be available to the American population on ... You and I talked previously about this idea of right to try.

Donald Trump: (15:32)

Right.

Speaker 7: (15:33)

Can we assure the American people that if it's being studied and it's in phase three, you have that right?

Donald Trump: (15:38)

That's a great question, and I'm not sure a lot of people have been thinking about right to try. We're all waiting for the final answer. Maybe I could ask Stephen, but I would say that right to try is exactly ... If somebody is virtually terminal, in other words they're not going to make it, and if we have these incredible therapies and drugs that are happening, Alex, I think it's a very interesting question. I congratulate you for that question because I think we're-

Speaker 7: (16:05)

Thanks, Mr. President.

Donald Trump: (16:05)

... all waiting for that exact final endpoint. What about that, Stephen? We have all of these seemingly great answers that are ready to come out, but because of the process, it takes a little- Can we use some of this early under Right to Try? Please.

Dr. Hahn: (16:18)

So it's a really good question. Of course, it all depends on the clinical circumstances and what a doctor and a patient together decide with respect to the administration of any agent.

Dr. Hahn: (16:29)

But if you think about what happened with convalescent plasma and the expanded access program, this is exactly what happened. We have ongoing clinical trials that are randomized between placebo or an inactive substance and the convalescent plasma. While that was going on, we knew that there was great demand from patients and doctors. The expanded access program is a way of actually doing that and fits perfectly with what the President just said about allowing people to be able to use something that we have now determined to be very safe.

Donald Trump: (16:57)

I think it was something we have to really consider very strongly.

Dr. Hahn: (17:00)

Yes, sir.

Donald Trump: (17:00)

I think it's fantastic. You should get credit for that.

Speaker 7: (17:04)

Thanks, Mr. President.

Donald Trump: (17:04)

Thank you. That's very good.

Speaker 8: (17:04)

Mr. President?

Donald Trump: (17:04)

Please, in the back. [OEN 00:17:08]?

Speaker 9: (17:10)

Thank you Mr. President. Convalescent plasma as a treatment has been around for nearly a hundred years. You mentioned Operation Warp Speed, which enabled this process to move along a lot faster. What went into the effort for this to be approved for COVID-19? And was that holdup political in nature?

Donald Trump: (17:30)

Well, I think that there might have been a holdup, but we broke the logjam over the last week, to be honest. I think that there are people in the FDA and actually in your larger department that can see things being held up and wouldn't mind so much. That's my opinion, a very strong opinion. And that's for political reasons. This has nothing to do with politics. This has to do with life or death. So we are being very strong, and we are being very forthright. We have got some incredible answers, and we're not going to let them be held up because every day is lives, and we're not going to let that happen. Okay? Very good, thank you.

Speaker 10: (18:06)

Mr. President?

Donald Trump: (18:06)

Please, go ahead.

Speaker 11: (18:10)

Mr. President, in announcing this today, you said that the FDA has made the independent determination that the treatment is safe and very effective. Yet Dr Hahn just said it was showing promising efficacy. Which of the two is correct?

Donald Trump: (18:25)

Well, I think I'll let Dr. Hahn answer that question.

Dr. Hahn: (18:29)

Under our legal authority for Emergency Use Authorization, this is not the same as an approval, but it's an authorization, and it allows us to expand the access to this. We know we're going to continue to collect data. We knew that for all of our Emergency Use Authorizations.

Dr. Hahn: (18:44)

So, for example, remdesivir, which was approved or authorized on May 1st, we're still collecting data, and we will continue to do that with plasma as well. So it's the nuances of the language around the authorization that we use and the legal aspect too.

Speaker 11: (18:57)

It's a promising treatment. You couldn't say it's very effective just yet.

Dr. Hahn: (19:02)

If you're one of those 35 out of 100 people who these data suggest or show survive as a result of it, this is pretty significant for that person and their family.

Donald Trump: (19:12)

Okay, this is a very big day. It's a day we've been looking forward to. Thank you very much. Great questions.

Speaker 12: (19:18)

Was there pressure on you, Dr. Hahn, to authorize this?

Speaker 13: (19:18)

Dr. Hahn?

Speaker 14: [\(19:18\)](#)

Mr. President [crosstalk 00:19:19]

Speaker 12: [\(19:19\)](#)

Dr. Hahn. Could you answer that question? [crosstalk 00:19:19] Dr. Hahn, to authorize this.

Speaker 12: [\(19:21\)](#)

(silence)

Other Related Transcripts

Transcript 7: Dr. Birx interview on Face the Nation, January 24, 2021:

2021-01-24 Face the Nation: Margaret Brennan interviewed Deborah Birx, M.D., *Face the Nation*, CBSNews. The abridged version that aired on *Face the Nation* on Sunday morning, January 24, 2021: <https://www.youtube.com/watch?v=odkIJGnhvhU> The complete interview of Dr. Birx by Margaret Brennan of *Face the Nation* of CBSNews: <https://www.youtube.com/watch?v=nW41YyIWipM>

236,131 views Jan 24, 2021

Former White House coronavirus response coordinator talks exclusively with "Face the Nation" in her first interview since leaving the Trump task force.

The Official CBS News abbreviated Transcript of the interview that aired Sunday, January 2021 on "Face the Nation":

The following is a transcript of an interview with former White House coronavirus response coordinator Dr. Deborah Birx that aired Sunday, January 24, 2021, on "Face the Nation."

The extended interview can be found [here](#), and heard as a special edition episode of the new "[Facing Forward with Margaret Brennan](#)" podcast.

MARGARET BRENNAN: Dr. Deborah Birx, the former White House Coronavirus Response Coordinator, is now at the CDC as a special advisor to the Center for Global Health. We sat down with her Friday--she had wanted to wait until after President Biden had taken office to talk about her time in the Trump administration.

MARGARET BRENNAN: The Biden coronavirus czar, for lack of a better term, told reporters, "When it comes to the vaccine, what we're inheriting is so much worse than we could have imagined." Is that a political statement? Is that accurate?

DR. BIRX: You know, I've been trying to process all the last 11 months because I- it's really important that we understand what worked and what didn't work. I took extensive notes during the entire process because I didn't want to lose track of what we need to do to make our response better in the future. One of those critical areas is this idea of federalism on which the United States was built. But that can be taken to extremes. And so the mantra always was federally supported and state-managed, locally executed.

MARGARET BRENNAN: That was the Trump plan?

DR. BIRX: That was the mantra. But what does support mean? And what does federal support mean? And I think really an understanding of what states need to translate guidance into implementation, what state needs- states need in interpreting data together. They only are seeing their data. But it's really important that they understand what's happening in their entire region because people have been mobile.

MARGARET BRENNAN: Do you think it's just bad architecture being handed off to the Biden administration? Are they being set up for failure?

DR. BIRX: Oh, I don't believe- and I- I- if I thought that was true, I wouldn't be sleeping right now because what was very important to me is from even before the election is to make sure that people had access to data and the data that we were seeing. And I think the more people can understand where the virus is, where it's increasing, where it's decreasing and react to even the slightest uptick. And that's a place where we're still slow.

MARGARET BRENNAN: Surveillance?

DR. BIRX: We're still slow in reaction. You need to react when you first see that tiniest little uptick in test positivity. That's the moment to tell that population. We need you to do these things.

MARGARET BRENNAN: You were often at odds with the CDC, is what I've been told. Is that true?

DR. BIRX: I know the CDC well, so it was diff- let me just be very clear, it was more difficult for them because I knew where the gaps were. And so when I came in, I really asked for those gaps to be addressed. I was also very pushy, and the one thing that's been taken completely out of context is when I was talking about not trusting the CDC data, it had to do with the ethnicity and race of the fatalities early on because of the delay in that reporting our delay for death certificates that have all that information on can be up to 30 days.

MARGARET BRENNAN: So, we're at the end of February. CDC official gives a briefing to reporters that tanks the markets when she says that within the community there may be a virus spreading and it could cause severe disruption to daily life. Dr. Fauci goes on television a few days later and says the risk to Americans remains low. You're watching this and what are you thinking?

DR. BIRX: So I'm in South Africa. we're yelling at the CNN television saying this is going to be a pandemic because the Chinese- what I saw from China, when you overwhelm your hospitals, you have to know that you have broad-based community spread before that happens. Yet they weren't seeing it. And that really worried me because what we were looking for is people with symptoms. And so when people were coming into the country, we were looking for people with symptoms.

MARGARET BRENNAN: But why wasn't it obvious to them, when you're watching this on TV and saying this is so clearly a pandemic that's coming to hit us hard?

DR. BIRX: I've learned from the things we've missed. This is exactly how we missed the HIV pandemic. If you're only looking for sick people, you miss a lot of the- what is really happening under the surface. And so I was always worried that there was a big iceberg under the surface and we were just seeing the top of it. So, when we were questioning people who came into this country about symptoms rather than testing everybody who came into the country, that's when I started to get really worried. At the same time there was a single individual in the White House that had been calling me since January.

MARGARET BRENNAN: That was Matt Pottinger,--

DR. BIRX: Yes.

MARGARET BRENNAN: --the Deputy National Security Adviser?

DR. BIRX: Because I have- I've known him and I've known his wife for a very long time. We've worked on pandemics together. Both of us were in Asia during SARS. And so we understood how serious this can go

MARGARET BRENNAN: Matt Pottinger asks you to come from the State Department to the White House.

DR. BIRX: And I said no about 20 times.

MARGARET BRENNAN: Why?

DR. BIRX: Well, from the outside, everything looks very chaotic in the White House. I had spent--

MARGARET BRENNAN: Wasn't it?

DR. BIRX: --the first three years of this administration trying to stay out of the swirl, trying to protect the PEPFAR program. We had extraordinary cuts, obviously, every year.

MARGARET BRENNAN: This is AIDS?

DR. BIRX: The President's Emergency Plan for AIDS Relief. It's what's changed the trajectory of the pandemic around the world, both for HIV and TB. I had no interest in going into a political space. I'm not a political person. I'm a civil servant. It never occurred to me to go into the White House until I could see that we were missing pieces that I thought were very important in the response. And so after many weeks of saying, no, no, no, the president announced the new task force with the vice president in the lead. They said this would be very technical, and that I would have a very technical position. And because I thought that I could be helpful, which is the only reason I go and do anything. If I think I have something to add, I feel like it's my obligation to the American public to go in and do that. That's what a civil servant is supposed to do.

MARGARET BRENNAN: You were a colonel in the Army?

DR. BIRX: Yes.

MARGARET BRENNAN: An immunologist, you were appointed by President Obama to work on AIDS relief, as you mentioned, at the State Department. Yet your name in the history books is going to be associated with President Donald Trump. How does that sit with you?

DR. BIRX: Well, you know, this is what worries me. If we start looking at technical civil servants as belonging to a political party, we will lose the ability for highly qualified civil servants to come and help. If we start saying if you come in and do this, you are then going to be part of the political apparatus, that is going to be very dangerous for this country.

MARGARET BRENNAN: Do you feel like your work is misunderstood as political?

DR. BIRX: I think pandemics are always political. That's what, I mean, I've worked in 60 countries. Every pandemic is political because you have to make policy changes to confront them, and policies are often political.

MARGARET BRENNAN: You worked on AIDS, which is a highly politicized virus--

DR. BIRX: Correct.

MARGARET BRENNAN: --in sub-Saharan Africa. But did any of that prepare you for the politics you encountered here with this pandemic in this White House?

DR. BIRX: No. No. White Houses function in a pretty- a pretty bureaucratic way, and most of the agencies function in a very predictable and bureaucratic way. But when you remove the infrastructure of the civil servants, then you end up with a lot more very quick right turns, left, turns, right turns, left turns, and that- that becomes less predictable and less able to manage that kind of response and change. And so that's why I kept extensive notes from every meeting, daily reflections to really understand what I was seeing. I wrote a daily report, over 310 of them that went to senior leaders. We created--

MARGARET BRENNAN: Did President Trump read them?

DR. BIRX: I don't know. I don't know. I sent them up through to the vice president. I had very little exposure to--

MARGARET BRENNAN: But you did brief President Trump?

DR. BIRX: I had very little exposure to President Trump.

MARGARET BRENNAN: Do you think President Trump appreciated the gravity of the health crisis you were describing?

DR. BIRX: I think the president appreciated the gravity in March. It took a while after I arrived in the White House to remove all of the ancillary data that was coming in. I mean, there was parallel data stream coming into the White House that were not transparently utilized. And I needed to stop that where people were--

MARGARET BRENNAN: You mean outside advisors?

DR. BIRX: Outside advisers, coming to inside advisors. And to this day, I mean, until the day I left, I am convinced there were parallel data streams because I--

MARGARET BRENNAN: Disinformation?

DR. BIRX: I saw the president presenting graphs that I never made. So, I know that someone- or someone out there or someone inside was creating a parallel set of data and graphics that were shown to the president. I know what I sent up and I know that what was in his hands was different from that. You can't do that. You have to use the entire database--

MARGARET BRENNAN: Who was doing that?

DR. BIRX: To this day I don't know. I know now by watching some of the tapes that certainly Scott Atlas brought in parallel data streams. I don't know who else was part of it, but I think when the record goes back and people see what I was writing on a daily basis that was sent up to White House leadership, that they will see that- that I was highly specific on what I was seeing and what needed to be done.

MARGARET BRENNAN: So the chief of staff is not saying, wait a second, this is our official coordinator listen to her and her only? Listen to you? No one was saying that?

DR. BIRX: No one said that to me.

MARGARET BRENNAN: To the president?

DR. BIRX: I- I don't know if they were saying it to the president.

(COMMERCIAL BREAK)

MARGARET BRENNAN: Welcome back to FACE THE NATION. We continue our conversation with Dr. Birx.

MARGARET BRENNAN: Do you think the president was just distracted by the political implications and the campaign?

DR. BIRX: You know, I always wonder that, and, I mean, the worst possible time you can have a pandemic is in a presidential election year. I think the White House personnel were very focused on this pandemic in March and April. I think once the country began to open and it was clear to me that they weren't going to follow my really gated criteria that I had worked hard on.

MARGARET BRENNAN: How to open restaurants, how to let people dine indoors--

DR. BIRX: I combined all of that together for these great gating criteria. So in calculating everything with the slow reopening, I didn't think anyone could get to Phase 3 until August. And you can see in the states that followed either that criteria or similar criteria, that's how long it took them.

MARGARET BRENNAN: Were there COVID deniers in the White House?

DR. BIRX: There are people in the White House and I think people around this country, because I've had the privilege to meet them and listen to them and hear them, because I wanted to hear what people were saying. There were people who definitely believed that this was a hoax.

MARGARET BRENNAN: Why?

DR. BIRX: I think because the information was confusing at the beginning. I think because we didn't talk about the spectrum of disease, because everyone interpreted on what they knew. And so they saw people get COVID and be fine.

MARGARET BRENNAN: So you don't blame the president's own language of calling some of this politically motivated, a hoax? It was a phrase he used at one point.

DR. BIRX: When you have a pandemic where you're relying on every American to change their behavior, communication is absolutely key. And so every time a- a statement was made by a political leader that wasn't consistent with public health needs, that derailed our response. It is also why I went out on the road because I wasn't censored on the road.

MARGARET BRENNAN: You felt the White House was censoring you?

DR. BIRX: Well, if you noticed, I was not able to do national press. The other thing that was very important to me is I was not going to go outside of the chain of command. And so if our White House comms group did not put me out, I didn't ask to go out. I- because there was so much leaking and so many parallel stories being leaked to the press that did not have grounding in truth that I didn't want to ever be part of that slippery slope. I know people started it with good intentions of trying to inform the American people, but then it became a way that they could silence those who didn't agree with them. And so I knew that every time I had a significant disagreement in the White House that within days a story would be planted.

MARGARET BRENNAN: Who was doing that?

DR. BIRX: I think a lot of people were doing that.

MARGARET BRENNAN: Do you think the administration was suppressing vital information to win the election?

DR. BIRX: I don't know what their motivation was. I know that I was so frustrated that I realized that the only way, if I could not get a voice internally, that I could get a voice out at the state level because I could see the governors on the governor's call weekly and I could see how deeply they were concerned about every one of their citizens. Most of them were not in the middle of an election campaign. I want to make it clear this was just not Debbie Birx. There was a coalition of- of four of us at the beginning, from Steve Hahn to Bob Redfield to myself to Tony Fauci. We would make sure that we could get the information out

to the public in one way or the other. It's why I sent the information to all of them every morning, because I never knew who would have the ability to do press.

MARGARET BRENNAN: Did you ever consider quitting?

DR. BIRX: Always.

DR. BIRX: I mean, why would you want to put yourself through that, um- every day? Colleagues of mine that I had known for decades- decades in that one experience, because I was in the White House decided that I had become this political person, even though they had known me forever. I had to ask myself every morning is there something that I think I can do that would be helpful in responding to this pandemic? And it's something I asked myself every night. And when it became a point where I could- I wasn't getting anywhere and that was like right before the election, I wrote a very detailed communication plan of what needed to happen the day after the election and how that needed to be executed. And there was a lot of promise that that would happen.

MARGARET BRENNAN: Because you knew at that point that the election was a factor in communication about the virus?

DR. BIRX: Yes. Yes.

MARGARET BRENNAN: Did you ever withhold information yourself?

DR. BIRX: No.

MARGARET BRENNAN: Some people felt you became an apologist for President Trump. They look at that moment in the briefing room

(BEGIN CLIP)

PRESIDENT DONALD TRUMP: *Then I see the disinfectant which knocks it out in a minute. And is there a way you can do something like that by injection inside or almost a cleaning?*

(END CLIP)

MARGARET BRENNAN: You were sitting there and he looked at you and he asked about ultraviolet light and heat--

DR. BIRX: See, that,--

MARGARET BRENNAN: --and you start talking about fevers. You didn't say no.

DR. BIRX: No, no.

(BEGIN CLIP)

PRESIDENT DONALD TRUMP: *Deborah have you ever heard of that? The heat and the light relative to certain viruses, yes, but relative to this virus?*

DR. BIRX: *Not as a treatment.*

(END CLIP)

DR. BIRX: He was not speaking to me. He was speaking to the DHS scientist that was two seats over from me that entire time. When he finally turned to me and said, is it a- could this be a treatment, I said, not a treatment. You can look at the transcripts. Not a treatment.

DR. BIRX: But that moment was- that was completely lost. And then there's, you know, skits on Saturday Night Live.

(BEGIN CLIP)

SATURDAY NIGHT LIVE CLIP: "DR. BIRX": *We all mess up sometime. You threw the ball wrong. I didn't say 'don't drink the bleach' It happens!*

(END CLIP)

Dr. BIRX: When you're a scientist who's grounded themselves in data and combating epidemics and working with communities and working with governments to change the future of people's lives for the better and then you get- this is what- when you talked about, was I prepared for that? No, I wasn't prepared for that. I didn't even know what to do in that moment.

MARGARET BRENNAN: Sometimes people say, well, Tony Fauci, when that happened to- to him, he would sort of gently come back up to the podium and set the record straight.

DR. BIRX: Well, he was given the opportunity to do that, though.

MARGARET BRENNAN: And you don't feel- you don't feel you were given the opportunity to respond?

DR. BIRX: Not until he turned to me and said, could this be a treatment? And I said, not a treatment. You know, people then want to define you by the moment and I understand- I, look, I understand how perceptions go. I understood that to go into the White House and try to support a comprehensive coronavirus response by utilizing the strength of the federal government would be a terminal event for my federal career, which is part of the reason why I didn't want to do it.

MARGARET BRENNAN: A terminal event?

DR. BIRX: A terminal event. I know that I wouldn't be allowed to really continue successfully within the federal government. You can't go into something that's that polarized and not believe that you won't be tainted by that experience or how people interpret you in that experience. So I knew that part of it. I didn't want that to happen.

MARGARET BRENNAN: And this will be the end of your federal career?

DR. BIRX: Yeah, I will need to retire probably within the next four to six weeks from CDC.

MARGARET BRENNAN: And how have you made peace with that, that this pandemic, that you're leaving in the midst of this, that you will be associated with it?

DR. BIRX: What was reassuring to me all along is I knew this would be studied. I knew that the emails, the reports that I wrote, the request to expand testing, the how to improve therapeutics, all of that, all of that would eventually come to light. Maybe not in my lifetime.

MARGARET BRENNAN: You feel you'll be vindicated?

DR. BIRX: I'm not looking to be vindicated. In that moment I think my service was important. I think it was important to make progress in testing. I think it was important in making progress with some of the therapeutics. And I think it was important to really- we had great innovation in vaccines. I was focused solely on the mission, and the mission was to try to save as many American lives during this pandemic as possible. And so I couldn't get distracted on vindicating myself or getting the information or telling the, you know, coming back to the press and saying that's not what happened. That would waste my energy in that moment of staying focused completely on that data and ensuring that I was seeing everything that was going on.

MARGARET BRENNAN: I read a Washington Post profile of you and it said, "When she's working on a vital public health issue, Birx will do whatever is necessary as long as she thinks she can make a difference."

DR. BIRX: True. And it hurt my family. You know, all of this- I have two daughters in their 30s who had to live through this and watch their mother, these things said about their mother, to become a skit, I mean. I have two grandchildren, daughters. You know, I think, I felt the whole time that I also had to be serious to be taken seriously, and I couldn't ever let emotion come into this, that no matter how frustrated I got, no matter how beaten down I got, I had to keep pushing as hard as I could. This tested my resilience because it tested my family and the things that were said that were so untrue, all of that about Thanksgiving.

MARGARET BRENNAN: You were accused of gathering with people outside your household because you went to a beach house with them?

DR. BIRX: There was no one outside of my household. I have one household. We happen to live between two houses because I had to protect them from me when I was out on the road. When I came back I quarantined. But if I had an emergency at that house, I wore a mask the whole time because I had to protect that household at all costs. I have a 92-year-old mother and a 96-year-old father and a- a daughter that's 38 weeks pregnant. And so the implication that I wouldn't follow CDC guidance- I followed CDC guidance and that's what protected me. I mean, I was on the road for six and a half months. I was in the White House during the hot- one of the hottest hot spots of viral transmission and I remained negative because I followed the CDC guidelines. That's why I know they work and that's why I take it very seriously.

MARGARET BRENNAN: Well, this summer, you gave an interview.

(BEGIN CLIP)

BIRX ON CNN: *"What we are seeing today is different from March and April. It is extraordinarily widespread."*

(END CLIP)

MARGARET: And then President Trump tweeted. He blasted you for saying that. Did you ever speak to him after that?

DR. BIRX: I hadn't seen him for months before that or months after that, but that was like--

MARGARET BRENNAN: You're the coordinator of the COVID Task Force.

DR. BIRX: --that was a- that was an extraordinary moment because I also got yelled out by the speaker, who I have tremendous I mean, obviously,--

MARGARET BRENNAN: Speaker Pelosi?

DR. BIRX: --women have gone through a lot to get in their positions. I have tremendous respect for women and women leadership.

MARGARET BRENNAN: Speaker Pelosi said she didn't have confidence in you because you were working for President Trump.

(BEGIN CLIP)

SPEAKER PELOSI ON CNN: *"I don't have confidence in anyone who stands there while the president says, 'swallow lysol, and it's going to cure your virus.' You know, it will kill you, and you won't have the virus anymore."*

(END CLIP)

DR. BIRX: And so that was very hard because I have known her from the HIV world, and I have tremendous respect for what she brought early on. So in my mind, she's a political hero for what she has done in HIV, which, you know, I've spent a lifetime on, along with TB--

MARGARET BRENNAN: So that stung?

DR. BIRX: Oh, that was hard. But she's not the only one, I think she gave voice to what a lot of people were thinking of, how could you? I think they looked at going into the White House as somehow supporting a political party or a political individual. There are technical people that are brought in for their technical expertise.

MARGARET BRENNAN: But you often were perceived as explaining some of the things President Trump said rather than correcting him.

DR. BIRX: Well, when people asked me a question, I feel like I have to respond with what my perception of that moment was.

MARGARET BRENNAN: When we come back, Dr. Birx talks about masks, or the lack thereof, in the White House.

(COMMERCIAL BREAK)

MARGARET BRENNAN: We want to pick back up with Dr. Birx, talking about the moment last spring when she and the task force realized that they had a serious problem.

DR. BIRX: Everyone knew that. Everyone knew that from, I would say, March- March 8th on. Because you only had to look at the slopes of the curves in these major metropolitan cities to understand what was happening and understanding if you're seeing that rate of hospitalization, how much community spread there was.

MARGARET BRENNAN: But you were trying to get Americans just to wear masks. And the president himself was undermining you. He wasn't wearing one. Is there ever a way to make that scenario work?

DR. BIRX: Well, you have to, because that's the president. So you have to figure out how to get that message out when you can't get it out from the head of the country. And that's our job. You don't give up. You can't ever in any moment when American lives are at stake, say, well, this is just too hard. I'm giving up.

MARGARET BRENNAN: But where's the vice president in all of this?

DR. BIRX: The vice president knew what I was doing.

MARGARET BRENNAN: You mean he knew that you were telling the governors privately to do things that the president publicly was making light of. When he was saying you don't really need to wear a mask, or pushing to reopen the economy faster than your guidelines would allow, Mike Pence knew that?

DR. BIRX: He knew what I was doing because--

MARGARET BRENNAN: And he supported it?

DR. BIRX: --I don't- I'm not a person who would go out on their own and not do, you know, I wouldn't go--

MARGARET BRENNAN: Why would you have to be sneaking around? You're the head of the COVID Task Force and tens of thousands of Americans are dying. Why is that a covert operation?

DR. BIRX: Because if this isn't working and you're not going to get that to work, you have to find another solution.

MARGARET BRENNAN: Leaving it up to the states, is that the way it should be in a pandemic, is the fundamental question?

DR. BIRX: Yes.

MARGARET BRENNAN: Tell me about some of the resistance from governors, because you're going out there and you're telling them to wear a mask, to limit indoor dining. And for some of these Republican governors, that would mean going against the head of their party to do what you're telling them to do.

DR. BIRX: You know, I don't know if that was as much as the dynamic as they were dealing with Republican legislatures and legislators. You needed every single level of government then to work together to ensure that, again, we're talking about behavioral change of American citizens.

MARGARET BRENNAN: How much responsibility lies on the shoulders of the governors running these states?

DR. BIRX: A lot. A lot. We have to be consistent. Sturgis was not okay. Birthday parties, not okay. Bringing together family members indoors, maskless, none of this. We have to be very clear to the community. And yes, we're going to make mistakes. We all make mistakes, we're human. If you made a mistake, if you had a gathering, at least get tested, wear a mask around those vulnerable, assume you got exposed and are infected and wear a mask around those vulnerable.

MARGARET BRENNAN: But how did the task force allow the president, who calls himself germaphobe, to get COVID himself? How did that happen?

DR. BIRX: There were only two people who regularly wore a mask in the White House.

MARGARET BRENNAN: Two people?

DR. BIRX: Myself and Tyler Ann McGuffee, the support person that I had from HHS.

MARGARET BRENNAN: So the staff around the president was not wearing a mask?

(BIRX SHAKES HER HEAD NO)

MARGARET BRENNAN: He's the commander in chief. This is a national security risk. How is that possible?

DR. BIRX: I think people believed testing- testing would be adequate.

MARGARET BRENNAN: So how is that possible?

DR. BIRX: I think they believe that testing is a surrogate for a public health intervention.

MARGARET BRENNAN: But did you say, "The President of The United States needs to wear a mask." Did you press Mike Pence on that? Did you press Mark Meadows, his chief of staff?

DR. BIRX: There are multiple communications about masking. Remember when I was talking about the stream of data coming in? They were mixing data that didn't have anything to do with the relevance of masking as a public health measure to changing into masking as a personal protective measure.

MARGARET BRENNAN: But did you ever say you're misunderstanding this? You need to wear a mask. These are close quarters and you're way too close to the President of the United States? You're nodding, yes, you had that argument?

DR. BIRX: Not with the president, I mean, I- I didn't have that kind of access, but to certainly people around the president. Yes.

MARGARET BRENNAN: And they just didn't take it seriously?

DR. BIRX: I just want to make it clear people were concerned about the president and wanted to protect the president. They believed that testing would be a reasonable substitution for people masking.

MARGARET BRENNAN: How sick did the president actually get?

DR. BIRX: I don't know. I don't know.

MARGARET BRENNAN: Did anyone ever say this is a national security risk and we need to nail down who brought this in and who infected the commander in chief?

DR. BIRX: I never heard those conversations.

MARGARET BRENNAN: There was no serious contact tracing that happened after the fact?

DR. BIRX: I don't know if there was contact tracing or not.

MARGARET BRENNAN: What was your biggest mistake?

DR. BIRX: I always feel like I could have done more, been more outspoken, maybe been more outspoken publicly- publicly. I didn't know all the consequences of all of these issues. When you're put into a new situation and you only know one person in the White House, you know, and you don't understand the culture of the White House, it's very difficult to get your footing. I'm not making excuses. I'm just saying I didn't know how far I could push the envelope.

MARGARET BRENNAN: You wish you pushed harder?

DR. BIRX: Yes.

MARGARET BRENNAN: We spent nearly 90 minutes talking to Dr. Birx. We'd been tested, and we were seated ten feet apart in a well ventilated facility. An extended version is available through our digital network, and in a special edition of our new podcast, FACING FORWARD.

Full interview: Dr. Deborah Birx on “Face the Nation” –(transcribed by Dr. Andrus between 10/23/2024 and 11/23/2024 from <https://www.youtube.com/watch?v=nW41YylWipM>)

Margaret Brennan: I want start on some of the news of the moment. On where we are with this virus. President Biden rolled out a number of actions on day 1: an executive order to wear a mask on federal property or traveling Interstate; requiring everyone on White House grounds to be tested; quarantining after international travel; forcing agencies to share data. What do you think of what he's done so far?

Dr. Birx: Well, certainly I'm fully supportive of all of those elements. I'm a strong supporter of masks and even mask mandates. I think mask mandates are really critical because you need that constant reminder. You're talking about, I mean, we're talking about our primary tools right now in addition to the vaccine is behavior change; and when you're asking people to change their behavior, you need those constant reminders. When I was on the road being reminded that I had to wear my mask was very helpful in the mask mandate States; and so, fully, I, and anything has to do with data I'm thrilled by. We have some very old databases. We used a lot of modeling rather than improving the collection of real time data. I think that's absolutely crucial; and I think the other innovations around really bringing people together. I think having what he didn't—well, one of the executive orders was around the White House coronavirus response coordinator and a deputy—I was an *n* of one, so having a team at the White House that can really respond to this is going to be really, really important because the amount of work that needs to be done not only at the White House but also at the state level to really ensure that we come out of this and some kind of normality by summer will be really critical.

Margaret Brennan: You said you were just one? You were coordinator of the task force--what do you mean you were just one?

Dr. Birx: There was only one full time person in the White House working on the coronavirus response.

Margaret Brennan: How is that possible?

Dr. Birx: Well, that's what I was given. So what I did is I went to my, my people that I've known all through the last years in government--all 41--and said, can you come and help me? And so I was able to recruit from other agencies, individuals and, certainly Irum Zaidi who I brought in from PEPFAR was my chief epidemiologist and data developer for the PEPFAR program where we really revolutionized data to really end the work on ending the pandemic of HIV and TB and in sub-Saharan Africa; and so I was be able to wicker together a group of volunteers who really helped me. And I had one incredible support person, Tyler Ann McGuffee, who really helped make sure I was at meetings on time and didn't miss emails; but there was no team--full time team--in the White House working on coronavirus.

Margaret Brennan: Did you ask for staff and you were denied?

Dr. Birx: I did ask for staff. Um --I think, what they're doing of bringing in an expert in testing, an expert in vaccines, an expert in data and data use, not just collecting data but how to use it successfully, I think all of those pieces are going to be critical for their success. Bringing in a fulltime supply-chain person, and so, all of these individuals existed but they existed in different pockets of governments. So as a team you're constantly having to work outward to getting everybody on board to making sure the responses as coordinated as it can be.

Margaret Brennan: On vaccines, the President says 100 million doses within 100 days. That's not 100 million Americans vaccinated. What do you think is actually possible? Is that too limited a goal?

Dr. Birx: Well, I know we, we haven't talked a lot, but I am very, very, very hard driving and relentless on where I think we need to go, and I would be thrilled to have 100 million people protected in 100 days.

Margaret Brennan: Actual shots—

Dr. Brix: --shots in arms, individuals in arms. I think it's really important to move vaccines as forward as fast as possible. I understand, and as I told them right after the election, there's not a lot of infrastructure behind a lot of these initiatives in the federal government right now; and, and, I know that they will bring in the infrastructure around that and so I think things will begin to accelerate; but we shouldn't hold ourselves back; and so we really need to ensure that states that are doing well can even do better, learn from those states, get that to other states; and I think getting more on the ground--learning it's why I went out in the field is to really understand what's working at the ground level.

Margaret Brennan: So, it sounds like you think it's a little modest as a goal, but the Biden Coronavirus Czar, for lack of a better term, told reporters when it comes to the vaccine what we're inheriting is so much worse than we could have imagined. Is that a political statement? Is that accurate?

Dr. Birx: You know, I've been trying to process all the last 11 months because it's really important that we understand what worked and what didn't work, and I think I've tried to pull all of this together, and I took extensive notes during the entire process because I didn't want to lose track of what we need to do, to make our response better in the future. One of those critical areas, and you're really getting to that essential point, is this idea of federalism on which the United States was built. But that can be taken to extremes; and so, the mantra always was federally supported and state managed, locally executed.

Margaret Brennan: That was the Trump Plan.

Dr. Birx: That was, that was the mantra--but what does support mean and what does federal support mean and, I think really, an understanding of what states need to translate guidance into implementation. What a state needs, states need in interpreting data together. They, they're seeing their data but it's really important that they understand what's happening in their entire region because people have been mobile. When we were out on the road, the interstates were filled with people traveling. And so I think this idea of how the--can the federal government be more supportive of the states not just delivering things but delivering new ideas and new innovations about how to make those things work better. And I think their intent, I hope their intent, is to do exactly that. It's why Irum Zaida and I went on the road. We went on the road because we wanted to figure out what states needed as far as federal support, how they were interpreting that guidance, [and] how communities were interpreting the CDC guidance.

Margaret Brennan: Time and again from the Trump administration, Secretary Azar, in particular, that they were getting that information from the states, that they were being responsive, that all of this was just playing politics when governors complained.

Dr. Birx: So we did work very hard to build a comprehensive data base not without a lot of scars over that last 11 months. It was really important to me personally because in order to have data that's reliable, it's not only the actual number but what the trend lines around that number is, and are there inflection points in the slope of the development of that number? And so, really, what we tried to bring together is all the testing data, all the case data, all the hospitalization data, and certainly all the fatality data to be able to constantly be triangulating data down to the most granular level because I think that's very important. So it's where you see success and you really see counties doing extremely well doing extremely well. Metro is doing extremely well. You gotta get to them then and learn from them because remember they're in the middle of trying to stop a pandemic--so they're working very hard with their citizens to stop a pandemic. If you want to learn from them, you need to physically go, see what they're doing, and bring those learnings back to other states. I think that's the approach that they're going to take. I think the past administration was focused very much on when we see a data problem, and when we see a problem, that's illustrated by the data like out of N95 masks, we ship them N 95 masks, but when you're talking about translating testing more proactively or strategically, you need real examples about how to do it better. You can't just send more tests, and I think that's the kind of learning that bidirectional learning between the States and the Federal government that I hope is gonna increase with the new administration.

Margaret Brennan: Do you think it's just that architecture being handed off to the Biden administration? Are they being set up for failure?

Dr. Birx: Oh, I do believe--If I thought that was true, I wouldn't be sleeping right now because what was very important to me is, from even before the election, is to make sure that people had access to data, and the data that we were seeing. And I have to say now I've been all over to every site that's been collecting COVID data, and I think the Atlantic COVID tracker site is actually superb. Americans should be following that because it gives trend lines. It just doesn't give numbers. It shows those trend lines over 7 days and I think the more people can understand where the virus is, where it's increasing, where it's decreasing, and react to even the slightest uptick, and that's a place where we're still slow.

Margaret Brennan: Surveillance.

Dr. Birx: We're still slow in reaction, and I think because in the early days we were so focused on flattening the curve and preserving the hospitals; that if the hospitals are OK, people have interpreted that they're doing OK. But you need to react when you first see that tiniest little uptick in test positivity. Test positivity even going up 0.1 to 0.3 to 0.5% tells you that you have expanding community spread. That's the moment to tell that population, that local population, we are seeing more community spread. We need you to do these things. Trouble is, we still are reacting late and that by the time we react the community spread is so widespread that then you have two to three to four weeks of really significant hospitalization rates and that always concerns me. We don't stop the virus early enough.

Margaret Brennan: The CDC director said that the health infrastructure is frail and poorly tended. She seems to be saying this is a problem that goes beyond President Trump that sounds like she's saying the infrastructure was rotting. Is that how you describe it?

Dr. Birx: Well, that's such an insightful point.

Margaret Brennan: You agree!?

Dr. Birx: Truly, it's a very insightful point because after federalism one of our biggest problems is we have a complete disconnect between what we call our clinical data systems: what happens at laboratories and hospitals and our public health data systems; and they don't interact in any way. So we had to fill these databases and data streams. We had to bring together public health data with clinical data, and that does not naturally exist in the United States.

Margaret Brennan: But we're the richest country in the world, how are we calling the CDC which is supposed to be the premier agency frail?

Dr. Birx: Because we haven't valued prevention; and we haven't taken on the difficult task of prevention early enough to really prevent some of these comorbidities. We're very good at identifying them; and the CDC has been great about saying this is where hypertension exists, this is where obesity exists, this is where our diabetes exist, this is where our overlapping comorbidities exist, but to really tackle that, you've got to have granular data and you've got to have it really frequently so you can see if your interventions are working. So, we have serious problems, but we're not tackling them in this deliberative data-driven way to really make changes. And I think what the new CDC director is recognizing: we have to really bring together our clinical and preventive responses and really be able to show impact. Because if you can show a governor which is why we also went on the road, if you can show the governor within two weeks of a mask mandate, Phoenix is cases began to drop dramatically. Then I can take that to another city and say this is what the Mayor of Phoenix did. Look at the impact it had--this is the data. They can see that then and then they can say to their population, the reason we're asking you to do this is because it works and it worked in Phoenix so we think it will work here in Tucson, and that's that's the kind of information that we need around obesity, hypertension, diabetes. We, we just can't keep ignoring these comorbidities that put Americans at significant risk.

Margaret Brennan: But some would hear you say that and say it sounds like you're blaming Americans?

Dr. Birx: Oh gosh, no.

Margaret Brennan: ..for their own health problems.

Dr. Birx: Never, never, these health—yes, certain health problems are genetic, for sure, but we have created a system that didn't value giving Americans the clear information and the clear ability to respond in a preventive way. We like to treat illness. We're not as good at prevention and that was very much illustrated in this pandemic, and I would never blame an American because I suffer from the same things; and, I, I guess I should be blaming myself. I mean, I was on the road I gained 15 lbs. I mean, I can tell you if you eat some of our food that's available to us regularly, you will gain weight. If you're immobile and you're driving around and you're eating McDonald's French fries all the time, it's not a good situation. I'm a direct experience of what that situation looks like and now I'm going to have to work at that; but encouraging people and showing that work results in outcomes and impact, people will change their behaviors. If they know what to do and they get positive reinforcement.

Margaret Brennan: You were often at odds with the CDC is what I've been told. Is that true?

Dr. Birx: I know the CDC well--let me just be very clear--it's more difficult for them because I knew where the gaps were; and so, when I came in I really asked for those gaps to be addressed; and a lot of it has to do with real time data and real time data acquisition and data revolution and data modernization to make things better so that the CDC, the premier public health agency, has daily information on how Americans are doing--not just in this pandemic but in general down to the zip code level so they can be very clear about what needs to be done. So, I was very pushy on that. I was also very pushy and the one thing that's been taken completely out of context is when I was talking about not trusting the CDC data, it had to do with the ethnicity and race of the fatalities early on because of the delay in that reporting. So, I was using the information from my European colleagues and I'm still deeply grateful to them of understanding who is most at risk for serious outcomes in this virus because our delay for death certificates that have all that information on can be up to 30 days. So when you're in the middle of a *pandemic* and it's gotten better, so that was the argument they never talked about what was being discussed before and what was being discussed after. I like to make real time data better and the way you make real time better data better is you use it.

Margaret Brennan: You said that you thought there might be an American strain of this virus circulating and the CDC says they don't have evidence of that. Are they wrong?

Dr. Birx: Well, there's two pieces of that. To be completely clear, so we certainly in this country had all this set up to develop the same kind of what we call more transmissible strains of the UK, Brazil, and, and, and South Africa. In fact, we had more capacity because we had more ongoing cases and infections continuously in the United States. So, this virus naturally mutates. It's constantly changing because it's an RNA virus. Some of it is just a mistake and it's a failure and that virus can no longer replicate. Other changes may make a competitive advantage--it's not like it's intellectually trying to make itself more fit, it's just by accident it makes these mutations-- they happen then to be more fit, more able to spread, and then you see this escape. So, the way you find them is you constantly are sequencing the underlying cases so you can look for what we call a nodal escape where it's enriched, where you see for these sequences in this area. So what we've done in molecular biology forever. We didn't have enough of those sequences. So what I was looking at is the rate of rise in the fall and the case fatality rate. So what I said and what I--so anything that I do personally--I increased my mitigation in October because I could see this rate of rise. So I wanted the governors to know what I was concerned about, and I said this could be. I didn't say we had one because of course until you have all the sequences you can't document it; but certainly the slope of the fall was twice as fast and it's lasting longer and critically, it's been more difficult to mitigate. So Texas and Arizona are doing exactly what they did in the summer that was able to control the spread and it's not having the same impact. You saw the same thing in LA. So what I wanted the governors to be able to know is we could have it but we should act like we do have it on two sides. We should be sequencing more to actually find if we do have it but at the same time we should be enhancing our mitigation and going to our communities and saying what's happening in the UK could be happening here and we just aren't seeing it yet. So let's act like we could and let's mitigate more.

Margaret Brennan: I'm going to talk about when you joined the COVID task force. So we're at the end of February, a CDC official gives a briefing to reporters that tanks the markets when she says that within the community there may be a virus spreading and it could cause severe disruption to daily life. Doctor Fauci goes on television a few days later and says the risk to Americans remains low. You're watching this and what do you thinking?

Dr. Birx: So, I'm in South Africa. We have all of our countries in from all over the world. We're going through, we're working 24 hours a day, but we have a break over dinner and we're staying in a place where we can cook and I love to cook. So, we're cooking, we're eating, we're watching CNN. And so over those two weeks of February, we're yelling at the CNN television saying this is going to be a pandemic because the Chinese, what I saw from China, when you overwhelm your hospitals, you have to know that you have broad based community spread before that happens. Yet, they weren't seeing it, and so from the minute I saw the hospitals in China, I was worried that there was large spread asymptomatic component to this coronavirus pandemic. And that really worried me because what we were looking for is people with symptoms. And so when people were coming into the country, we were looking for people with symptoms.

Margaret Brennan: When you say: we, who do you mean I mean:?

Dr. Birx: The United States

Margaret Brennan: The CDC?

Dr. Birx: The United--well the--I think it was everybody. I don't know who was on the task force at that time, but I think multiple agencies were represented at that time.

Margaret Brennan: But why wasn't it obvious to them when you're watching this on TV and saying this is so clearly a pandemic that's coming to hit us hard?

Dr. Birx: I guess because I've been in a lot of pandemics and I've learned from the things we've missed, this is exactly how we missed the HIV pandemic. That's how we missed it when it started. I know that it's not a respiratory disease but it has a large asymptomatic component and so we didn't see it until people started getting sick. That's true about many pandemics. If you're only looking for sick people, you miss a lot of the what is really happening under the surface. And so I was always worried that there was a big iceberg under the surface and we were just seeing the top of it. So when we were questioning people who came into this country about symptoms rather than testing everybody who came into the country, that's when I started to get really worried. At the same time there were individuals--a single individual in the White House that had been calling me since January. It was Matt Pottinger, the Deputy National Security Adviser, because I've, I've known him. I've known his wife for very long time. We worked on pandemics together. Both of us were in Asia during SARS and so we understood how serious this can go. And I think, I think there was a level of belief that our technology would really save us from this. You know that we would be able to find all the infections or stop all the infections, but when you have an asymptomatic component, the only way you find them is proactive testing.

Margaret Brennan: And he asked you. Matt Pottinger asks you to come from the State Department to the White House.

Dr. Birx: And I said no about 20 times.

Margaret Brennan: Why?

Dr. Birx: From the outside, everything looks very chaotic in the White House. I had spent the first three years of this administration trying to stay out of the swirl. Trying to protect the PEPFAR program. We had extraordinary cuts obviously every year. This is the president's emergency plan for AIDS relief. It's what's changed the trajectory of the pandemic around the world both for HIV and TB. And I'm very proud of the work that the community--and I say that community: Global Fund, UN AIDS, WHO, PEPFAR together, along with our HIV advocates and the community groups around, around the world. We've been able to

tackle this, but it took all of us together working together, and I had spent three years just trying to protect the program and keep my head down and get my work done. I had no interest in going into a political space. I'm not a political person. I'm a civil servant. I've never been a political person. I've never worked on a campaign. I've never campaigned for any of the candidates. I take the Hatch Act very seriously. I, I just am not a political person. So, it would, it never occurred to me to go into the White House until I could see that we were missing pieces that I thought were very important in the response, and so after many weeks of saying no, no, no, the President announced the new task force with the Vice President in the lead. Um, they said this would be very technical and then I would have a very technical position and because I thought that I could be helpful, which is the only reason I go and do anything, if I think I have something to add I feel like it's my obligation to the American public to go in and do that. That's what a civil servant is supposed to do.

Margaret Brennan: Do you feel you made a difference?

Dr. Birx: Yes.

Margaret Brennan: How?

Dr. Birx: I think the biggest difference was over the testing. So, as soon as I, I arrived March 2nd, I talked to the Vice President. I said these are the three gaps I think we have. They have to be addressed this week. Every day that goes by, we get further behind. You cannot confront this epidemic by primarily testing as we have in flu by small conformational testing and public health labs. When they were approaching it as a flu pandemic because that is what we expected to happen in the United States. Testing is utilized to confirm about every month thousands or every 100,000 cases. Flu is diagnosed by symptoms.

Margaret Brennan: But Dr. Fauci, Dr. Redfield from the CDC, they were there.

Dr. Birx: But, you know, when you're in the midst of it and they were very much focused on preventing infections from coming into the United States. They were very focused on that-- looking for those symptomatic cases. I thought what I could bring--I had a lot of experience in RNA viruses, RNA virus testing development, vaccine development, but, most importantly, experience in trying to get government to work in government to work efficiently and effectively and change management; and, I can tell you, change management in the federal government is very different than change management in the public sector, in the private sector. And so I wanted, I thought, I could bring some of those skills, and my focus on being able to read data and reading able to see changes early so that people could be alerted early.

Margaret Brennan: So you, as you mentioned, have been a public servant. You were a Colonel in the army.

Dr. Birx: Yes

Margaret Brennan: An immunologist. You were appointed by President Obama to work on AIDS relief as you mentioned at the State Department; yet your name in the history books is going to be associated with President Donald Trump. How does that sit with you?

Dr. Birx: Well, you know this is what worries me. When I see how partisan and divided the United States is. That then gets played out in the Civil Service; and, if we start looking at technical civil servants as belonging to a political party, we will lose the ability for highly qualified Civil Servants to come and help, and we have amazingly qualified Civil Servants: they're at the CDC, they're at HHS, they're at FDA, they're at NIH, and most of *the White House* personnel are Civil Servants detailed there from their home agencies. If we start saying, if you come in and do this, you are then going to be part of the political apparatus. That is going to be very dangerous for this country.

Margaret Brennan: Do you feel like your work is misunderstood as political?

Dr. Birx: I don't--I think pandemics are always political. That's why, I mean, I've worked in you-know 60 countries. Every pandemic is political because you have to make policy changes to confront them, and policies are often political.

Margaret Brennan: I mean, you've worked on AIDS which is a highly politicized in sub-Saharan Africa, but did any of that prepare you for the politics you encountered here with this pandemic in this *White House*

Dr. Birx: No, no, and I feel like it's still difficult for me because I pride myself in being able to always find a way, find a way, or make one. When this doesn't work, you go this way. When that doesn't work, you go this way, you find another set of alliances. *The White House* functions in a purely, a pretty bureaucratic way, and most of the agencies function in a very predictable and bureaucratic way; but when you remove the infrastructure of the Civil Servants, then you end up with a lot more very quick right turns, left turns, right turns, left turns, and then that becomes less predictable and less able to manage that kind of response and change. And, so I think in some ways people will say, you know disrupting and change is very important; and yes, disruption and change and inflection points in American history are important; and it's important to recognize those and build on those; but it also in a pandemic can be very, very difficult then to get us back always to the response that we need to have and being able to point out here's where the problems are coming from. That said, I was privileged to work with a whole series of both political and technical people from all of the agencies: the CDC was enormously helpful, the FDA, the NIH, and the teams that were working on vaccines--these are dedicated Civil Servants who gave everything to this pandemic; and so, I think, as the other thing, I knew is this was historic. So that's why I kept extensive notes from every meeting, daily reflections to really understand what I was seeing, I wrote a daily report--over 310 of them that went to senior leaders, we created...

Margaret Brennan: Did President Trump read them?

Dr. Birx: I don't know. I don't know. I sent them up through to the Vice President...

Margaret Brennan: You didn't expose that trump

Dr. Birx: I had very little exposure to President Trump.

Margaret Brennan: So, you were looking at all this data. Do you think when you were in the room and briefing, even if it was with other people, do you think President Trump appreciated the gravity of the health crisis you were describing?

Dr. Birx: I think the President appreciated the gravity in March. It took a while after I arrived in *The White House* to remove all of the ancillary data that was coming in. I mean there was parallel data streams coming into *The White House* that were not transparently utilized, and I needed to stop that.

Margaret Brennan: We're, we're pumping outside advisors?

Dr. Birx: Outside advisers coming to inside advisers... and to this day, I mean, till the day I left, I am, I'm convinced there were parallel data streams because...

Margaret Brennan: Disinformation?

Dr. Birx: I saw the President presenting graphs that I never made. So, I know that someone or someone out there or someone inside was creating a parallel set of data and graphics that were shown to the President. I don't know to this day who, but I know what I sent up, and I know that what was in his hands was different from that. That worries me because, at any moment, I've built my career on data transparency and accountability. It is very important to me that we all agree how the data is collected and how we use it, use it. We don't cut it in pieces and say we're only going to look at it in this six weeks because it doesn't look better, and we're only going to look at it at these two weeks because we look better than Europe in these two weeks. You can't do that. You have to use the entire database.

Margaret Brennan: Who was doing that?

Dr. Birx: To this day, I don't know. I know now, watching some of the tapes, that certainly Scott Atlas brought in parallel data streams. I don't know who else was part of it, but I think when the record goes back and people see what I was writing on a daily basis that was sent up to the White House leadership, that they will see that that I was highly specific on what I was seeing and what needed to be done.

Margaret Brennan: So the chief staff is not saying, wait a second, this is our official coordinator: listen to her and her only--listen to you? No one was saying that?

Dr. Birx: No one said that to me.

Margaret Brennan: To the president?

Dr. Birx: I- I don't know if they were saying it to the president.

Margaret Brennan: Do you think the President was just distracted by the political implications in the campaign?

Dr. Birx: You know, I always wonder that, and, I mean, the worst possible time you can have a pandemic is in a presidential election year. I just want to be frank there's politics, and there's policies, and there's pandemics, but in an election year, everything takes on a different perspective. I think *The White House* personnel were very focused on this pandemic in March and April. I think once the country began to open and it was clear to me that they weren't gonna follow my really gated criteria that I had worked hard on, and the reason that gating criteria was so important to me is it combined the insights of Tom Frieden with Zeke Emanuel and Scott Gottlieb. I took--they had the three Sentinel papers on how to open America safely,

Margaret Brennan: How to open restaurants, how to let people...

Dr. Birx: I combined all of that together for these great gating criteria. So in calculating everything with the slow reopening, I didn't anyone could get to phase three until August and you can see in the states that followed either that criteria or a similar criteria, that's how long it took them. And by then, we had the fall surge coming, I wanted to keep the summer quiet so that we could build capacity to get to what we all knew would be a much more difficult fall.

Margaret Brennan: What were the biggest obstacles to you communicating that though--I mean, were there COVID deniers in *The White House*?

Dr. Birx: There are people in *The White House* and I think people around this country because, I've had the privilege to meet them and listen to them and hear them because I wanted to hear what people were saying--there were people who definitely believed that this was a hoax.

Margaret Brennan: Why?

Dr. Birx: I think because the information was confusing at the beginning. I think because we didn't talk about the spectrum of disease. Because everyone interpreted on what they knew, and so they saw people get COVID and be fine. And then they had us talking about how severe the disease is and how it could cause these unbelievable fatalities of our American public. I mean, so every American life lost--I mean, I haven't slept in 10 months or 11 months because those were the numbers--that's someone's parents, that's someone's grandparent, my great grandmother was lost in the pandemic flu, I know what that feels like from just listening to my grandmother--to have that other--feel that same level of pain and loss when it was preventable or could be preventable, it was really excruciating. So...

Margaret Brennan: So, you don't blame the President's own language of calling some of this politically motivated, a hoax, the phrase he used at one point?

Dr. Birx: You know when you have a pandemic, where you're relying on every American to change their behavior, communication is absolutely key; and so every time a statement was made by a political leader that wasn't consistent with public health--that derailed our response. It is also why I went out on the road because I wasn't censored on the road. I was able to speak freely about mask mandates, closing bars when you're in the middle of a surge, closing indoor spaces where people are going to take off their masks and be inside. We know that those are spreading events.

Margaret Brennan: You felt *The White House* was censoring you?

Dr. Birx: Well, if you've noticed, I was not able to do national press. The other thing that was very important to me is I was not going to go outside of the chain of command, and so if our *White House* comms group did not put me out, I didn't ask to go out because there was so much leaking and so much parallel stories being leaked to the press that did not have grounding in truth, that I didn't want to ever be part of that slippery slope. I know people started it with good intentions of trying to inform the American people but then it became a way that they could silence those who didn't agree with them, and so I knew that every time I had a significant disagreement in *The White House* that within days a story would be planted.

Margaret Brennan: Who was doing that?

Dr. Birx: I think a lot of people were doing that.

Margaret Brennan: And meanwhile Americans are dying--10s of thousands, hundreds of thousands at this point. I mean, there was a long stretch of time right before the election where we didn't hear from you. We didn't hear from Doctor Fauci. We didn't hear in the public space from Doctor Redfield. In the midst of this national crisis, do you think the administration was suppressing vital information to win the election?

Dr. Birx: I don't know what their motivation was. I know that I was so frustrated by the end of May going into June by the lack of reaction to what I could see in the middle of May coming, that it, and that combined with the gating criteria not being utilized, that I realized that the only way if I could not get a voice internally, that I could get a voice out at the state level because I could see the governors on the governors call weekly and I could see how deeply they were concerned about every one of their citizens. Most of them were not in the middle of an election campaign and so by going out and working with the governors, two things happened: One, I got to see amazing things that are best practices and really bring those back and what I've learned from Detroit and Chicago and Arkansas and Alabama and Texas and Arizona and up through Connecticut--I mean it's just been amazing to be able to see really great solutions and try to bring those back, but that was the place where people would let me say what needed to be said about the pandemic both in private with the governors and then in following up doing press to talk to the people of that state. They also would let me do regional press. And really, I want to thank the coms team who let us go out regionally to speak to people and states when I could see changes coming and the comms team every week would ask me for a list--where were, where were my concerns and then 10 individuals or so went out that week and did and just blanketed regional press to really say these are the things you need to do. It was difficult during the during the run up to the election. That was the time when one of my daily reports--there was by that time 200 of them--that was when one of them was leaked right before the election--so clearly, there was some intentionality there and I was talking about how severe the epidemic was in the northern plains States and saying if that epidemic gets into our populist states of California, Texas, Florida, New York, that this would be an early surge to what we expected in the winter with the expansion of this virus, and so I was very worried. But others were worried too. I want to make it clear, this was just not Debbie Birx. There was a coalition of, of four of us at the beginning, from Steve Hahn to Bob Redfield to myself to Tony Fauci that making it clear that we would, we would make sure that we could get the information out to the public in one way or the other. It's why I sent the information to all of them every morning because I never knew who would have the ability to do press.

Margaret Brennan: Did you ever consider quitting?

Dr. Birx: Always, I mean, why would you want to put yourself through that every day? Colleagues of mine that I've known for decades, decades, in that one experience because I was in *The White House* decided that I had become this political person even though they had known me forever. I- I had to ask myself every morning, is there something that I think I can do that would be helpful in responding to this pandemic? And it's something I asked myself every night and, when it became a point where I could I wasn't getting anywhere and that was like right before the election, I wrote a very detailed communication plan of what needed to happen the day after the election and how that needed to be executed and there was a lot of promise that that would happen.

Margaret Brennan: Because you knew, at that point, that the election was a factor in communication about the virus.

Dr. Birx: Yes, yes.

Margaret Brennan: Did you ever withhold information yourself?

Dr. Birx: No.

Margaret Brennan: Some people felt you became an apologist for President Trump. They look at that moment in the briefing room, you know the one I'm talking about, when he came out and he talked about injecting bleach and you were sitting there and he looked at you and he asked about ultraviolet light and heat.

President Trump (from archive footage): Debroah, have you ever heard of that the heat and the light relative to certain viruses, yes, but relative to this virus?

Dr. Birx (from archive footage): That is a treatment...

Dr. Birx: See, and that...

Margaret Brennan: And you start talking about fevers. You didn't say that no.

Dr. Birx: No, OK, so let's go back to that because that's a really critical moment. He was not speaking to me. He was speaking to the DHS scientist that was two seats over from me that entire time. When he finally turned to me and said--is it a--could this be a treatment? I said not a treatment. You can look at the transcripts--not a treatment. That dialogue was between the President of the United States and the DHS scientist. I have always been respectful of offices and you can see I don't criticize people specifically in public. I- I don't think that, that I always think that you need to transcend that and you need to find a way to communicate effectively where you're not criticizing a person in public. So, when he did turn to me at the very end of that dialogue, I said not a treatment. Now it's in the transcripts--it never got picked up by the press as that is what actually happened.

Margaret Brennan: Your answer when he said bleach, you said: Not a treatment.

Dr. Birx: Not a treatment. When he turned to me and said what do you think could this be treatment, I said: Not a treatment; but that moment was, that was completely lost, and then there's you know skits on Saturday Night Live.

Saturday Night Live Clip: "Dr. Birx": We all mess up sometime: you threw the ball wrong. I didn't say don't drink the bleach

Dr. Birx: I mean when you're a scientist who's grounded themselves in data and combating epidemics working with communities and working with governments to change the future of people's lives for the better and then you get this is what when you talked about. Was I prepared for that? No, I wasn't prepared

for that. I didn't even know what to do in that moment. I think that's when you're in that: can't the floor swallow you up moment. I mean that conversation between two people was going on in front of me and I- I, to this day, don't know what to do when that happens. Now, I- I think there's some people who thought that I would just stand up and take over the microphone from the President. I don't know what people's expectations were in that moment.

Margaret Brennan: Well, sometimes people say: well, Tony Fauci, when that happened to him, he would sort of gently come back up to the podium and set the record straight, if he disagreed with the President.

Dr. Birx: Well, he was given the opportunity to do that.

Margaret Brennan: And you don't felt, you don't feel, you were given the opportunity to?

Dr. Birx: Not until he turned to me and said: Could this be a treatment? And I said: Not a treatment. You know, and in that moment, people then wanted to define you by the moment; and I understand, I understand, look I understand how perceptions go; and I understand, I understood when Matt Pottinger was calling me, that to go into *The White House* and try to support a comprehensive coronavirus response by utilizing the strength of the federal government would be a terminal event for my federal career--which is part of the reason why I didn't want to do it.

Margaret Brennan: A terminal event.

Dr. Birx: A terminal event--I know that I wouldn't be allowed to really continue successfully within the federal government. You can't go into something that's that polarized and not believe that you won't be tainted by that experience or how people interpret you in that experience. So, I knew that part of it. I didn't want that to happen but, you know, I had to psychologically prepare myself for that event because, and that was the discussion I was having in South Africa with my colleagues, that if I go and do this, there will be really no option to return to PEPFAR or to return to my home agency, the CDC. I had always planned on retiring after 40 years. I ended up staying a little bit longer to get through this.

Margaret Brennan: And this will be the end of your federal career.

Dr. Birx: Yeah, I will need to retire probably within the next four to six weeks from the CDC.

Margaret Brennan: And how have you made peace with that--that this pandemic was a once-in-100-years pandemic that is projected to kill half a million Americans by the middle of next month that you're leaving in the midst of this--that you will be associated with it? Have you thought and digested that?

Dr. Birx: Well, what I do know and what was reassuring to me all along is I knew this would be studied. I knew that the emails, the reports that I wrote, the request to expand testing, the how to improve therapeutics, all of that, all of that would eventually come to light—maybe, not in my lifetime.

Margaret Brennan: You feel you'll be vindicated?

Dr. Birx: I'm not looking to be vindicated. I'm looking to be able in that moment, I think, my service was important. I think it was important to make progress in testing, I think it was important in making progress with some of the therapeutics, and I think it was important to really--we had great innovation in vaccines--I also wanted to make sure that we had some of the tried and true vaccines under development. And so there are, there are places where I know I had an impact; but that's not--I never allowed myself--I was focused solely on the mission and the mission was to try to save as many American lives during this pandemic as possible. And so I couldn't get distracted on vindicating myself--or getting the information--or telling--or coming back to the press saying that's not what happened. That would waste my energy in that moment of staying focused completely on that data and ensuring that I was seeing everything that was going on, so that I could convey that not only to the federal leadership but convey it directly down to the states. It's why we started writing the governor's report. There were just four of us that wrote that it took us all weekend but it was worthwhile because it said to the governor this is what we're seeing nationally, and this is what we're

seeing specifically in your state, and it was a dialogue that allowed us to come to a common understanding of what we were seeing and what they were seeing of how to work together more effectively.

Margaret Brennan: I read a Washington Post profile of you and it said when she's working on a vital public health issue Birx will do whatever is necessary, as long as she thinks she can make a difference.

Dr. Birx: True. And it hurt my family--you know, all of this. I have two daughters in their 30s who had to live through this and watch their mother--these things said about their mother, to become a skit. I mean I have two grandchildren daughters, you know. I think I felt the whole time that I also had to be serious to be taken seriously and I couldn't ever let emotion come into that no matter how frustrated I got, no matter how beaten down I got, I had to keep pushing as hard as I could. And I think Matt Pottinger knew that I'm very resilient but this tested my resilience because it tested my family and the things that were said that were so untrue--all of that about Thanksgiving.

Margaret Brennan: You were accused of gathering with people outside your household because you went to a beach house with them.

Dr. Birx: Yeah, there, there was no one outside of my house. I have one household. We happen to live between two houses because I had to protect them from me when I was out on the road. I couldn't let myself, because I, when I came back, I quarantined. Yes, I relied on testing at day 5-6 and seven which eventually CDC came to part of the guidance, but if I had an emergency at that house, I wore a mask the whole time because I had to protect that household at all cost. I have a 92 year old mother and a 96 year old father and a, and a daughter that's 38 weeks pregnant. I had to do what was necessary for the country but I also had to protect my family, and so the implication that I won't follow CDC guidance--I followed CDC guidance and that's what protected me. I mean I was on the road for 6 1/2 months. I was in *The White House* during the hot one of the hottest spot spots of viral transmission and I remained negative because I followed the CDC guidelines. That's why I know they work and that's why I take it very seriously.

Margaret Brennan: Did any of your children and ask you to quit?

Dr. Birx: No, they knew what I was trying to do. You know I'm very lucky to have two daughters that believe their mother can make a difference and so they would never ask me to do that because they know that I would leave if I felt I was ineffectual.

Margaret Brennan: Well this summer you gave an interview. Then you went silent for a while.

Dr. Birx on CNN: It is extraordinarily widespread.

Margaret Brennan: And then President Trump tweeted. He blasted you for saying that. Did you ever speak to him after that?

Dr. Birx: I hadn't seen him for months before that or months after that, but that was like that was...

Margaret Brennan: You were the coordinator of the COVID task force.

Dr. Birx: That was an extraordinary moment because I also got yelled at by the Speaker who I have a tremendous, I mean obviously...

Margaret Brennan: Speaker Pelosi?

Dr. Birx: ...women have gone through a lot to get in their positions. I have tremendous respect for women and women leadership. I know what they've had to go through to get to where they are. I also have now much more respect for women who are involved in journalism because when I was on the road I could see that dynamic. It's also why I started calling on all the women first because you know they would be out shouted sometimes by their male colleagues. I mean, it's difficult out there. Gender is still a very real and

very difficult piece, but I wanted women to know that you can work, you can be a scientist, you can hold your head high, and you can help. And I think we do bring a different piece to the puzzle because we're always concerned about our families and that community piece in a way that sometimes our male colleagues aren't, and that's not a criticism, it's just how fundamentally we function in the American Society.

Margaret Brennan: Speaker Pelosi said she didn't have confidence in you because you were working for President Trump.

Speaker Pelosi on CNN: I don't have confidence in anyone who stands there while the President says swallow Lysol, and it's going to cure your virus. You know, it will kill you, and you won't have the virus anymore. I am not have confidence somebody when the President says it's a hoax, it's magic, it's going to go away by magic, it's a miracle, and all of those things.

Dr. Birx: And so that was very hard because I've known her from the HIV world and I have tremendous respect for what she brought early on. So in my mind, she's a political hero for what she has done in HIV which I've spent a lifetime on a lot.

Margaret Brennan: So that stung.

Dr. Birx: Oh, that was hard, but she's not the only one. I think she gave voice to what a lot of people were thinking of how could you--I think they looked at going into *The White House* as somehow supporting a political party or a political individual. There are technical people that are brought in for their technical expertise.

Margaret Brennan: But you often were perceived as explaining some of the things President Trump said rather than correcting him.

Dr. Birx: Well when people ask me a question, I feel like I have to respond with what my perception of that moment was, and so there were three sentinel or four sentinel events that I think I'm highly criticized for: One of them is the 40,000 ventilator issue.

Margaret Brennan: This was the governor of New York saying he needed 40,000. You said, no you don't. You need something like 4000. So this is in the, in the heat of the moment in the spring.

Dr. Birx: Yeah, but that started the whole cascade of...that's when I had to stop looking at Facebook and Instagram because in that moment, they interpreted that as me supporting the President when what I was saying was you're using an unmitigated model, and, yes, that's how bad things could be if you weren't mitigating but you were mitigating so your need is going to be significantly less. And the reason that was important in that moment is that in that moment, we had 12,000 ventilators in the stockpile.

Margaret Brennan: That's it?

Dr. Birx: We had 16,000--four of them were in maintenance, 4000; we had 12,000 ventilators but when New York said they needed 40,000 at the same time, then governors started calling from all over the country saying, well I need 10 and I need 20. By the end of that first week, with that one Governor Cuomo announcement, there was a request for almost 100,000 ventilators.

Margaret Brennan: And we had a fraction of that in the US stockpile.

Dr. Birx: And so, what I was worried about is people would start to panic about not having access to the care that they needed, and so it was our job to try to figure out what other options there were from splitting access to ventilators so two people on one ventilator, utilizing anesthesia ventilators, utilizing high throughput, high volume O₂ outside of ventilation. We had it--that was a very critical mad scrambling event for myself, and I think many others, and I just want to thank many people who came forward and said this

is, this is a solution, this is a solution, and that is a solution, but we also remodeled what people would absolutely need.

Margaret Brennan: Was that the moment, though that, that moment in the spring, is that the moment you looked at the task force and you said we have a serious problem here? This is not going according to plan.

Dr. Birx: That everyone knew, that everyone knew that from, I would say, March 8th on because you only had to look at the slopes of the curves in these major metropolitan cities to understand what was happening and understanding if you're seeing that rate of hospitalization how much community spread there was.

Margaret Brennan: But you were trying to get Americans just to wear masks and the President himself was undermining you. He wasn't wearing one. I mean, you would go out and talk about it—it can be a fashion statement from the podium. I mean, you were trying to make it light so people would accept it, but all these guidelines are getting undermined by the President himself. Is there ever a way to make that scenario work?

Dr. Birx: Well, you have to because that's the President. So you have to figure out how to get that message out when you can't get it out from the head of the country--and that's our job. You don't give up. You don't say: Well, that didn't work. so, of course, you know everything is gonna be terrible. You gotta try to make it the least terrible it can be. I mean you can't ever, at any moment, when American lives are at stake say well this is just too hard--I'm giving up.

Margaret Brennan: But where's the Vice President in all of this?

Dr. Birx: The Vice President knew what I was doing.

Margaret Brennan: You mean he knew that you were telling the governors privately to do things that the President publicly was making light of. When he was saying you don't really need to wear a mask, or pushing to reopen the economy faster than your guidelines would allow, Mike Pence knew that?

Dr. Birx: He knew what I was doing because—

Margaret Brennan: And he...

Dr. Birx: --I don't--I'm not a person who would go out on their own and not do, you know, I wouldn't go...

Margaret Brennan: Why would you have to be sneaking around? You're the head of the COVID task force and 10s of thousands of Americans are dying. Why is that a covert operation?

Dr. Birx: Because if this isn't working and you're not going to get that to work, you have to find another solution. I mean, you can't just say well the President is saying this, so I'm going to give up on the 50 States, the District of Columbia, and the territories that we support. I couldn't do that. I mean I and others couldn't either. I mean there was a team of people going out and supporting this approach. I felt all along that if we could have put 20 or 30 full-time CDC personnel in every State for long term assignments: six, six months assignments, they could help States get over these barriers and understand and help support States to translate their guidance.

Margaret Brennan: But the CDC didn't do that. They didn't want to do that?

Dr. Birx: They sent people out for short, short term and these are the kinds of things--because that's what their historically used to doing. I think these are the things we have to work on in the long run of how we really respond to a pandemic which is part of the reason why I'm going to take time to really reflect on this, organize all my thoughts, and put together what really worked, what could be expanded, what kind of legislative fixes do we need. Are we in a...do we accept federalism when public health being able to save Americans with a comprehensive national public health response is critical.

Margaret Brennan: Leaving it up to the states--is that the way it should be in a pandemic is the fundamental question?

Dr. Birx: Yes.

Margaret Brennan: So when you were going out there to the governors, I mean, tell me about some of the restrictions, some of the resistance from governors because you're going out there and you're telling them to wear a mask, to limit indoor dining, and for some of these republican governors that would mean going against the head of their party to do what you're telling them to do.

Dr. Birx: You know, I don't know if that was as much as the dynamic as they were dealing with republican legislatures and legislators that really didn't--and it's why I started meeting with the legislature and it's why I started meeting with county commissioners because you needed every single level of government then to work together to ensure that--again we're talking about behavioral change of American citizens--everyone then had to endorse it: the governors, the mayors, the county commissioners. I was in States in the middle of this country where the senior public health person, the senior public health person said to me why don't you believe that we should go for herd immunity.

Margaret Brennan: Meaning just let everyone get sick and see how it plays out.

Dr. Birx: Because in many of the farm lands you do that sometimes when you have a really bad swine virus or you let it run through the herd and rebuild the herd with resistant.

Margaret Brennan: And you said we're dealing with human beings and, and lives...

Dr. Birx: Yes, but I mean you have to, you have to let people talk about what they're thinking. You have to be able to provide environment where people can honestly say what they are thinking because then you can't confront it. If we keep that everything is fine and we're not listening to people and listening for where they're coming from, we're not going to make the changes that we need in order to be successful.

Margaret Brennan: Sturgis, this motorcycle rally in the middle of South Dakota, thousands of people gathered with no masks. How much responsibility lies on the shoulders of the governors running these States like that in South Dakota?

Dr. Birx: A lot, a lot but let's recognize what's happening right here, right now in the District of Columbia. There are National Guard troops here from every State in the Union probably. Young individuals who are most likely to have asymptomatic infection if they do get infected; and their congregately living and eating maskless, 25 to 30,000 of them from all over the United States.

Margaret Brennan: Do you think this inaugural gathering is a massive super spreader event?

Dr. Birx: It could be. When you bring 30,000 people together where you know that they're most likely to have asymptomatic infections and you haven't pre screened, pretested, serially tested all of these troops. These are dedicated troops. They're gonna do their mission, I can promise you that. They will sacrifice their own health to do their mission because that's the, that's what I came from-- you sacrifice for others out of the military. They will do their mission.

Margaret Brennan: But then, I mean you compare this where people may or may not be tested but they're wearing masks--you compare that to the Super spreader event that was wearing masks.

Dr. Birx: Did you see the pictures of the National Guard? They can't wear masks. They're communally eating and communally sleeping.

Margaret Brennan: When they're eating and sleeping...

Dr. Birx: So we have to be careful in every single thing. There shouldn't be, it's okay here and not OK there. We have to be consistent. Sturgis was not OK. Birthday parties—not OK. Bringing together family members indoors maskless, none of this, we have to be very clear to the community and—yes, we're going to make mistakes. We all make mistakes, we're human. If you made a mistake, if you had a gathering, at least get tested, wear a mask around those vulnerable, assume you got in those are infected and wear a mask around those vulnerable. So if you went to Sturgis, you should have worn a mask when you came home. If you got exposed potentially here when you go home until you're 10 days out and you avoid getting with your vulnerable family members. We, that's what I do to really ensure that you're protecting each other.

Margaret Brennan: How did the task force allow the President who calls himself a germaphobe to get COVID himself? How did that happen?

Dr. Birx: There were only two people who regularly wore a mask in *The White House*: myself and Tyler Ann McGuffree.

Margaret Brennan: Who's that?

Dr. Birx: My, the support person that I had from HHS.

Margaret Brennan: So the staff around the President was not wearing a mask. He is the commander-in-chief--this is a national security risk. How is that possible?

Dr. Birx: I think people believed, wrongly that testing, testing would be adequate.

Margaret Brennan: How is that possible?

Dr. Birx: I think they believed that testing is a surrogate for a public health intervention. I think testing is critically important and equal to masking and physical distancing and hand washing because I think testing allows you to see the silent epidemic, and you can't find them unless you're proactively testing. So I'm a strong proponent of testing, more testing, and testing people who have no symptoms.

Margaret Brennan: Did you say the President United States needs to wear a mask? Did you press Mike Pence on that? Did you press Mark Meadows, his chief of staff?

Dr. Birx: There are multiple communications about masking and this gets into the data issue. Remember when I was talking about the stream of data coming in. People were interpreting the hospital mask data: the difference between an N95, KN 95, surgical mask, and cloth mask to say that cloth masks don't work because in this hospital setting it didn't work. That was different--remember in a hospital setting, you're trying to protect the nurse or the doctor from what's out here. We were asking people to wear a mask to protect others from them, so it was a very different context and so they were mixing data that didn't have anything to do with the relevance of masking as a public health measure to changing into masking as a personal protective measure.

Margaret Brennan: But did you ever say you're misunderstanding this, you need to wear a mask? These are close quarters and you're way too close to the President of the United States. You're nodding yes--you had that argument.

Dr. Birx: Not with the President, I mean, I I didn't have that kind of access, but to certainly people around the President—Yes.

Margaret Brennan: And they just didn't take it seriously?

Dr. Birx: They believed that the testing protocol would be adequate to protect the President. , I just want to make it clear, people were concerned about the President and wanted to protect the President. I don't want you to think understanding that there were frivolous people in *The White House*. That people were

very concerned about the President. They believe that testing would be a reasonable substitution for people masking.

Margaret Brennan: How sick did the President actually get?

Dr. Birx: I don't know, I don't know, I don't know, but I can say that certainly they thought he was sicker than the first lady because they wanted to get him additional therapy.

Margaret Brennan: Do you think his life was in danger?

Dr. Birx: And just to be very clear, what we know in the data for people over 70 even today, about 18 to 19% of people over 70 who get this virus are hospitalized. And of all people over 70 who get this virus, 10% of them succumb to this virus--one in 10--to me, that's a very, very serious illness. If you knew that your parents had a one in 10 chance of dying from a virus as I do, you would do everything to protect them. The president was over 70. So do I believe that adequate constant public health surveillance and measures were put into place based on his age alone not have been taking into account everything else? No, but they weren't put in place for the entire country and that was what my message was.

Margaret Brennan: Did anyone ever say this is a national security risk and we need to nail down who brought this in, and who infected the commander-in-chief?

Dr. Birx: I never heard those conversations.

Margaret Brennan: There was no serious contact tracing that happened after the fact?

Dr. Birx: I don't know if there was contact tracing, or not. I, you know, it's not something that I was responsible for. The health and welfare of the President falls to *The White House* medical team. I know many of those individuals. They are very serious individuals. I am sure that they took this seriously. I know they took his care very seriously. I knew they took the care of the first lady very seriously. This virus, I think people really just couldn't wrap their heads around, that you could have a virus that caused almost no disease--such mild disease that the person didn't think they were even infected and they were spreading the virus to others and such severe disease that it could kill your grandparents. And I think that's still hard for people to wrap their heads around because if they have the experience of losing a parent or grandparent, they understand the severity of the disease. If they only see the disease from their college students who got it and there were no consequences in the moment.--We still don't know what kind of chronic, what we would call, morbidity could come from this when there are 20 or 30 years older. We don't know and we just should be really honest we don't know that mild disease might not lead to significant long term health crisis or health consequences. We don't know that. So we feel like that communication piece was never really understood at a level to really push people to action.

Margaret Brennan: What was your biggest mistake?

Dr. Birx: Well, I'm categorizing what I think all of them going back through all of my notes from 11 months to really try to understand where I could have been better. When, I think there is, I could I always feel like I could have done more; be more outspoken, maybe been more outspoken publicly, publicly. I didn't know all the consequences of all of these issues when you're put into a new situation and you only know one person in *The White House*. You know and you don't understand the culture of *The White House*. It's very difficult to get your footing. I'm not making excuses. I'm just saying, I didn't know how far I could push the envelope. I'm known for doing that--particularly in private, but it was very difficult for me at day one to really understand that and that's the kind of piece we needed from day one.

Margaret Brennan: You wish you pushed harder?

Dr. Birx: Yes.

Margaret Brennan: On anything in particular?

Dr. Birx: Well, fundamentally, testing. I mean I- I really believe that proactive testing as we've seen happen in universities--universities that tested weekly at a minimum of every student, required testing not voluntary testing, or required testing independent symptoms had infection rates of about 10% of what the universities that tested the way we do in the United States focused on people who have symptoms. Letting people who want to come in and get a test, get a test, where you're testing a lot of worried well that may not even have exposure but not routinely making sure that young people in the community are repetitively tested so you can find the asymptomatic infections. Young people are responsible and they will isolate if they know they have the virus, but you cannot expect them to be isolated as young adults if they don't have the virus, and it's our job to figure out how to make testing available for them. And then the final piece is making things too complicated. I went out right before Christmas to six States because I was worried that the this highly sophisticated tearing of individuals was going to be really difficult for States to act.

Margaret Brennan: You mean, how States are setting the guidelines on who gets the vaccine--you think it's overly complicated?

Dr. Birx: I think it's very complicated.

Margaret Brennan: But that came from federal guidelines.

Dr. Birx: But, in a pandemic, you have to simplify things. You have to make it so States have an easy way to do it and document it that the right people are getting the immunizations. And we knew, it's not that we didn't know who was at greatest risk for severe disease. We knew that, we know that, we know that today, and I think we were trying to balance the fabric of society with those at greatest risk; but when you're in the middle of a surge and, you know that before Christmas we had an unbelievable surge across the entire country, I went out right before the holidays to talk to governors and say if you're willing to think about simplifying this, think about immunizing everybody over 65, just do your healthcare workers absolutely, they're on the front lines but then everybody else: do by age because we know that that's the risk of severe.

Margaret Brennan: Would you tell governors now: Do that, throw out whatever new federal guidelines the Biden administration issues and just go with large portions of the population.

Dr. Birx: What we see states that are being successful in doing that. I, one of my first states I went to was West Virginia because they're rapid adopters--you know they really looked at their population. The other thing that wasn't taken into account is: every state has a different population of percent of their population that's over 65 and it ranges from 11% to over 22%, and so not only do you have to like insure that they can have access to vaccine, but you need to then redo how you're putting out vaccines so that the States that have a higher proportion of individuals over 65 get more vaccine than the States by population that have only 11%. I mean, you've got to really adjust to make sure that there's equity and so I- I think some of the States have figured this out. They're, they and the, the proof will be in the pudding, did they save more lives? I am very, I'm encouraged that our numbers are going in the right direction. It's says to me that Americans are trying their best to follow the guidelines, and I- I hope and I believe that they will continue to understand that masks work; and, if we have more contagious virus, masking more will have even a greater impact and a critical impact along with the physical distancing and hand washing, washing but we need to do more testing and we really need to ensure that we can support the States and their vaccine delivery.

Margaret Brennan: Thank you for, for your time.

Transcript 4:

Attachment H: 2021-02-16 U.S. Food & Drug Administration: Clinical Memorandum. COVID-19 Convalescent Plasma EUA Decision Memo.

<https://www.fda.gov/media/141480/download> is the baseline URL which when placed in the Wayback Machine, 8-23-2020 to 2-2021 is the renewed new memo on CCP EUA issued 2-2021 to the present:

<https://web.archive.org/web/20210330024720/https://www.fda.gov/media/141480/download>

EXECUTIVE SUMMARY

COVID-19 Convalescent Plasma (CCP) was granted Emergency Use Authorization (EUA) for the treatment of hospitalized patients with COVID-19 on August 23, 2020. At that time, the totality of the scientific evidence supported a determination that the use of CCP in hospitalized patients with COVID-19 met the “may be effective” standard for issuance of an EUA, and it was reasonable to consider that the known and potential benefits of CCP outweighed the known and potential risks for the authorized use.

Following the EUA, emerging evidence from randomized controlled trials has continued to inform this assessment. The available evidence indicates that 1) the use of low titer CCP in hospitalized patients no longer meets the evidentiary standard of “may be effective”, and 2) **high titer CCP has not demonstrated benefit when administered late in the disease course in immunocompetent hospitalized patients.**

Additional data from RCTs and observational studies support a determination that **high titer CCP may be effective when administered early in the course of illness, particularly prior to the expected time of host antibody response.** In patients with impaired humoral immunity, the potential therapeutic window may be prolonged. As RCT data continue to demonstrate that the risks of CCP do not exceed those observed with plasma transfusion in general, it is reasonable to believe that the known and potential benefits of use of high titer CCP outweigh the known and potential risks when used for the treatment of hospitalized patients with COVID-19, particularly early in the course of illness or in patients with impaired humoral immunity. Results from ongoing RCTs are expected to continue inform the optimal patient populations and product characteristics for efficacy of CCP in COVID-19.

Recommendation: The conditions of Emergency Use Authorization for CCP for the treatment of hospitalized patients with COVID-19 should be revised to exclude the use of low titer CCP. High titer CCP continues to meet criteria for Emergency Use Authorization for the treatment of hospitalized patients with COVID-19 **early in the course of hospitalization.** The letter of authorization and accompanying fact sheets should be revised to emphasize early administration of CCP in the absence of immunodeficiency or immunosuppression. Additional results from adequate and well-controlled trials will continue to be evaluated to further characterize the patient populations and product characteristics meeting EUA criteria

.....

Antibody responses in COVID-19 and timing of CCP transfusion

The relative roles of humoral and cellular immunity in SARS-CoV-2 infection continue to be unraveled, and it appears likely that CD4+ T cells, CD8+ T cells, and neutralizing antibody responses all contribute to control of SARS-CoV-2 infection in both non-hospitalized and hospitalized cases of COVID-19[23]. The large majority of patients with SARS-CoV-2 infection will seroconvert within 5-15 days post-symptom onset, with 90% seroconverting by day 10[23-25]. IgM and IgG antibodies are frequently detected concurrently[26], and peak anti-spike or anti-RBD IgG levels are reached by approximately 15 days post symptom onset[27]. Antibody

responses and memory B cells appear to persist for at least 5 months and antibodies may be a correlate of immune protection[28-31]. Delayed antibody response kinetics also appear to be associated with more severe disease[27, 32]. At the same time, studies have generally shown higher titers in patients following recovery from severe disease compared to mild or asymptomatic illness[25, 33].

The observation that high titer CCP was beneficial when administered within 72 hours of symptom onset in high risk subjects, but failed to demonstrate benefit in trials where the median duration of symptoms was 8 days or longer, indicates benefit with CCP transfusion is more likely in patients early in the humoral immune response when host antibody titers remain undetectable or low (i.e., likely within the first week following symptom onset). This is consistent with longstanding historical precedent in passive immune therapies for viral infections, where prophylactic or early use has generally been more effective than in established infections[34].

These trends are also consistent with clinical evidence for administration of anti-SARS-CoV-2 monoclonal antibodies, where benefit has been demonstrated with early outpatient use, but not in hospitalized patients within 12 days of symptom onset[35-37] as described in the following two studies:

In outpatient studies of bamlanivimab in recently diagnosed patients with mild to moderate disease (BLAZE-1)[36], subjects were excluded if they were previously known to be seropositive. Subjects had a median of 4 days of symptoms at the time of infusion, and the study found one of three doses of neutralizing antibody LY-CoV555 appeared to accelerate the natural decline in viral load over time. While reduction in viral load was the primary endpoint in this phase 2 trial, subjects treated with bamlanivimab also showed a nominally statistically significant reduction in COVID-19 related hospitalizations or ED visits within 28 days in the pooled dose-level data.

In outpatient studies of casirivimab/imdevimab in symptomatic patients with mild to moderate COVID-19 (R10933-10987-COV-2067), subjects who were no more than 7 days from symptom enrollment were included regardless of serostatus[35]. Casirivimab/imdevimab treatment reduced viral load, and patients who were seronegative at baseline showed larger reductions in viral load and a larger reduction in the proportion of subjects with at least one medically attended visit compared to the overall population. Based on these studies, both therapies were granted EUA for use in high risk outpatients with mild to moderate COVID-19 (<https://www.fda.gov/media/143892/download>, <https://www.fda.gov/media/143603/download>).

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In early studies of the COVID-19 pandemic, the median time from symptom onset to the development of dyspnea was approximately 5-8 days[38, 39], and patients who develop critical illness typically do so shortly thereafter (days 8-10)[40]. While the study by Libster et al[10] demonstrated a reduction in progression to severe disease in high risk outpatients within 72 hours of the onset of symptoms, one factor complicating very early use of CCP in the outpatient population is the evidence that a large proportion of these patients will have a self-limited illness and will not go on to severe or critical illness even without targeted intervention[41]. Therefore, in the early-disease outpatient population, it is important to have a full understanding of the relative benefit and identify high-risk populations so that the known and potential risks of transfusion are outweighed by the known and potential benefits of CCP. Ongoing randomized controlled trials will be critical to determine the clinical and laboratory parameters that can identify where the potential benefit of CCP outweighs the potential risk in outpatients.

Based on the study by Libster et al[10] the therapeutic window appears to be at least within 72 hours of symptom onset, while additional negative RCTs with a median duration of symptoms prior to transfusion of 8 days indicating that 8 days after symptom onset may be too late for

efficacy of CCP in immunocompetent hospitalized COVID-19 patients. These timepoints appear to correlate with the timing of the patients' own antibody responses to infection, such that by the time a patient is forming their own antibodies, benefit from CCP appears unlikely. The time period between 3 and 7 days remains to be studied rigorously in randomized trials of CCP, but observational studies, preclinical studies, studies of related therapies, and what is known about the timing of the adaptive immune response in SARS-CoV-2 infection suggest that high titer CCP may be effective in this window period. As noted above, this window appears to be longer in the setting of impaired or deficient humoral immunity. Nonetheless, adequate and well controlled trials in this time period remain necessary for a conclusive demonstration of efficacy.

- 742) 2021-02-05 Dockser Marcus A: FDA Limits Use of Convalescent Plasma as Covid-19 Treatment. Agency to scale back authorization of the antibody-rich blood component after studies yielded mixed results. The Wall Street Journal Feb 5, 2021.
<https://www.wsj.com/articles/fda-limits-use-of-convalescent-plasma-as-covid-19-treatment-11612537239>

[This article is copied verbatim from the Wall Street Journal with annotations so as to translate what is meaningfully being said by those interviewed!].

The Food and Drug Administration [is scaling back its authorization](#) of the use of convalescent blood-plasma for Covid-19 patients in an effort to guide physicians who have faced a confusing thicket of data about the therapy's effectiveness.

The agency said late Thursday that the authorization, [a subject of controversy since it was first issued last August](#), would be revised to limit the use of plasma to [hospitalized patients early in the course of the disease](#) and [hospitalized patients with a medical condition that impairs their ability to make antibodies](#). Patients will be allowed to receive [only plasma containing high concentrations of antibodies](#).

"The update is meant so convalescent plasma can best be used on those who will benefit," said Peter Marks, director of the FDA's Center for Biologics Evaluation and Research. "It is being used somewhat more indiscriminately." ***[High-titer COVID-19 Convalescent Plasma should be given to everyone becoming COVID-19 positive within <72 hours. – NOT just those hospitalized.—C. Andrus]***

Dr. Claudia Cohn, chief medical officer of AABB, an organization representing the transfusion-medicine community, said the group plans to issue interim recommendations on convalescent plasma later this month. "There are so many studies coming out with different conclusions," she said. "It is not clean, it is not black and white."

Dr. Marks said the FDA reached its decision after evaluating results from several recent studies. Some showed benefits from convalescent plasma, the antibody-containing fluid derived from the blood of people who have recovered from Covid-19. Others showed no benefit.

Two clinical trials of convalescent plasma for hospitalized patients shut down last month after investigators said there appeared to be no benefit. Three trials involving hospitalized patients recently reported some benefit for the plasma, but only when given to patients soon after admission. ***Still another trial showed that elderly outpatients given plasma shortly after showing symptoms were less likely to develop serious disease. --- [This was the January 6, 2021 publication in The New England Journal of***

Medicine which is the ONLY Prospective randomized, placebo controlled trial of CCP administration in one cohesive age group (~70 years of age). THIS IS A LANDMARK STUDY! – C. Andrus]

Arturo Casadevall, chair of molecular microbiology and immunology at the Johns Hopkins Bloomberg School of Public Health, called the FDA decision “a step forward.” He said, “Physicians in the U.S. for the first time are going to have guidance on when to use it and how to use” convalescent plasma.

Dr. Casadevall is a co-founder of the Covid-19 Convalescent Plasma Project, which helped [organize a nationwide expanded-access study of convalescent plasma](#) that began last April.

Despite the contradictory findings, convalescent plasma remains in demand—in part because there are few effective treatments for Covid-19 and many people remain unvaccinated. Since the FDA issued the emergency authorization last August, the blood industry has distributed on average about 20,600 units of convalescent plasma a week to hospitals around the country, according to the American Red Cross.

The FDA’s earlier decision to authorize [convalescent plasma for hospitalized Covid-19 patients](#) was based in large part on results from an agency-sponsored [expanded-access program](#), through which more than 72,000 patients received plasma. For a study published last month in the New England Journal of Medicine, researchers analyzed data from 3,000 of those patients and reported an apparent survival benefit among hospitalized patients not on mechanical ventilation who received plasma containing high concentrations of antibodies.

But many scientists expressed skepticism about that finding, saying expanded-access studies lack the scientific rigor of traditional trials because they have no control group to compare any apparent effect.

The FDA’s Dr. Marks said the authorization of convalescent plasma “could have been handled much better. It had to do with the sense of urgency everyone is feeling. I can’t blame anyone for feeling a sense of urgency.” -- [As Dr. Marks is the Director of the FDA’s CBER (Center for Biologics Evaluation and Research), it was his sole responsibility to have handled it better from March 2020 to the present for the biologic: COVID-19 Convalescent Plasma which is a biosimilar biologic to rabies vaccine, gamma globulin, RhoGam, hypertet, small pox convalescent plasma, IVIG, FFP, etc., etc., etc!]

Dr. Marks also said the data could be confusing. Each unit of convalescent plasma is unique, reflecting the immune response of the recovered patient who donated it. It took time to figure out the best way to measure the antibodies in a unit, he added.

The U.S. isn’t the only government trying to establish reliable guidelines on the use of convalescent plasma. In Argentina, a study in elderly outpatients published last month in the New England Journal of Medicine contributed to current recommendations there to treat elderly Covid-19 patients early in the course of their illness. “Plasma supplies are not endless, and invariably public health officials face difficult decisions,” said study co-author Dr. Fernando Polack of Fundación Infant in Buenos Aires. “In any of these decisions, guidelines based on data are necessary and are the best way for clinicians to feel comfortable when facing individual cases.”

Louis M. Katz, chief medical officer of Mississippi Valley Regional Blood Center in Davenport, Iowa, which provides blood products for over 120 hospitals, said the evidence supporting the use of convalescent plasma in hospitalized patients is weak. **“I think the data is there that it works early,”** he said. **“As you move into sicker and sicker people, the evidence gets thinner and thinner.”**

In an editorial that accompanied the New England Journal of Medicine paper on the U.S. expanded-access study, **Dr. Katz said convalescent plasma should be used only in patients early in the course of the disease**. The problem with that suggestion, he later added, is the FDA emergency-use authorization still covers only hospitalized patients, who tend to show up at the hospital when they have been sick for a longer time. **– [This is the problem, to become hospitalized, most patients have to be very sick and thus outside the <72 hour window! – C. Andrus, M.D.]**

Treating Covid-19 patients who are just starting to show symptoms poses its own challenges. “Logistically, it is very difficult to treat patients earlier,” Dr. Katz said. **“It’s hard to transfuse lots of plasma in outpatients.” [BUT IT CAN BE DOWN IN INFUSION CENTERS or Hospital outpatient centers as is done for all infusion chemotherapies, chronic blood transfusions, etc! – C. Andrus. M.D.]**

Dr. Marks said a large National Institutes of Health study is now under way to test convalescent plasma in people with Covid-19 who are sick enough to come to the emergency room but aren’t admitted to the hospital, as are other randomized controlled trials of plasma in outpatients. “Until we have those data, we are going to keep the authorization to hospitalized patients,” he said. **“We will refine it again if appropriate. This is a scarce resource.” [High-titer COVID-19 Convalescent Plasma should NOT be a scarce resource as it can be obtained twice a week from the same convalescent donor by PLASMAPHORESIS and the product from each donation will yield 2 doses (4 doses per week) and it can be stored as FFP (Fresh Frozen Plasma) for at least a year! In short, there are over 5,000 blood banks in the US so if each Blood Bank processed 20 units a day of COVID-19 Convalescent Plasma, that would be:**

20 donations / day times 7 days/week times >5000 U.S. Blood Banks times 2 doses of CCP / donation = greater than 1.4 million doses per week of CCP
– C. Andrus, M.D.]

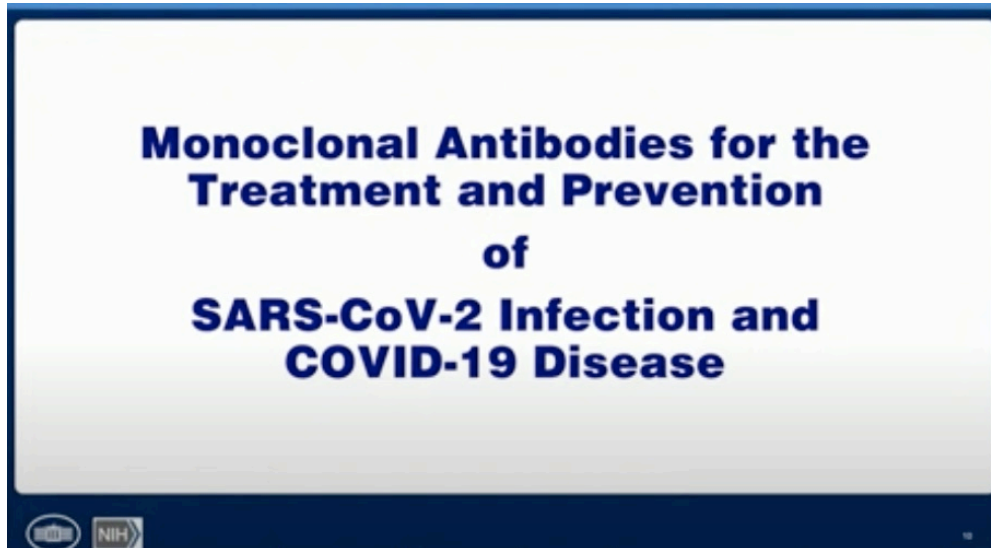
Write to Amy Dockser Marcus at amy.marcus@wsj.com
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Appeared in the February 6, 2021, print edition as 'FDA Limits Plasma as Treatment.'

Transcript 5: **08/24/21: Press Briefing by White House COVID-19 Response Team and Public Health Officials**

<https://www.youtube.com/watch?v=AZNP05w2cxU>

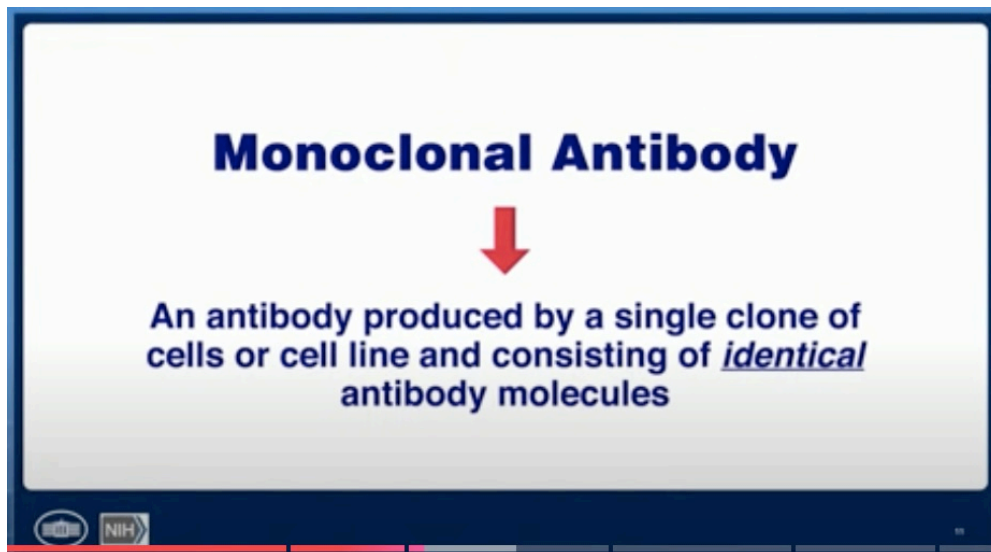
Dr. Fauci: Thank you very much Dr. Walensky.



I would like to spend the next couple of minutes in addressing a much underutilized intervention for COVID-19, and that is the use of monoclonal antibodies for the treatment and prevention of SARS-CoV-2 to infection and

COVID-19 disease.

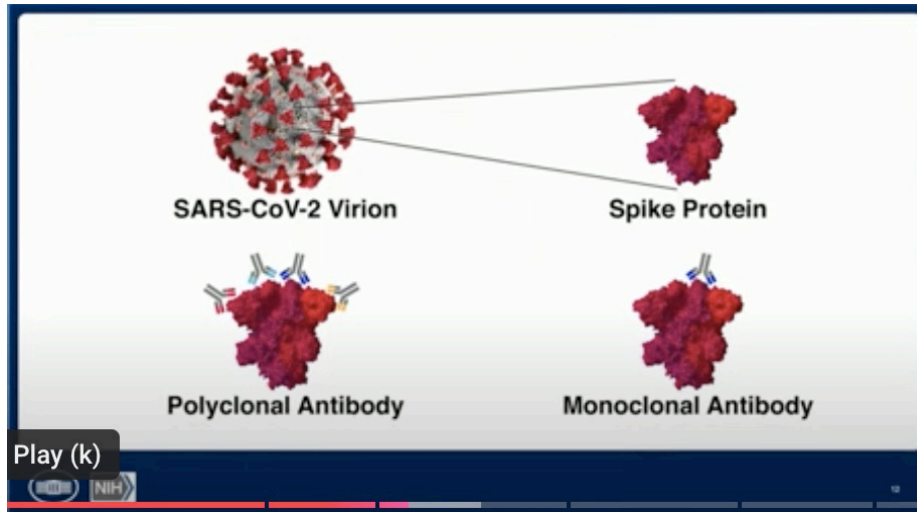
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Those not totally familiar with this monoclonal antibody is an antibody produced by a single clone of B-cells or a cell line and consists of identical antibody molecules that can actually be produced in the in vitro situation

in unlimited quantities.

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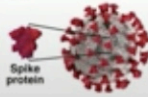
If you look at the virion on the upper left part of the slide and you look up at the blown up spike protein-- the red molecule on the right upper panel, when you talk about polyclonal antibodies which result from infection or vaccination, it's a group of antibodies against every aspect of

the spike protein which is the good news. However, the concentration and the affinity of those antibodies can be markedly improved if you get a single cloned antibody—hence, the word monoclonal that's against the very specific part of the spike protein that can have a major effect in prevention and treatment.

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3 Anti-SARS-CoV-2 Monoclonal Antibody Products Currently Have Emergency Use Authorizations (EUAs) From the FDA

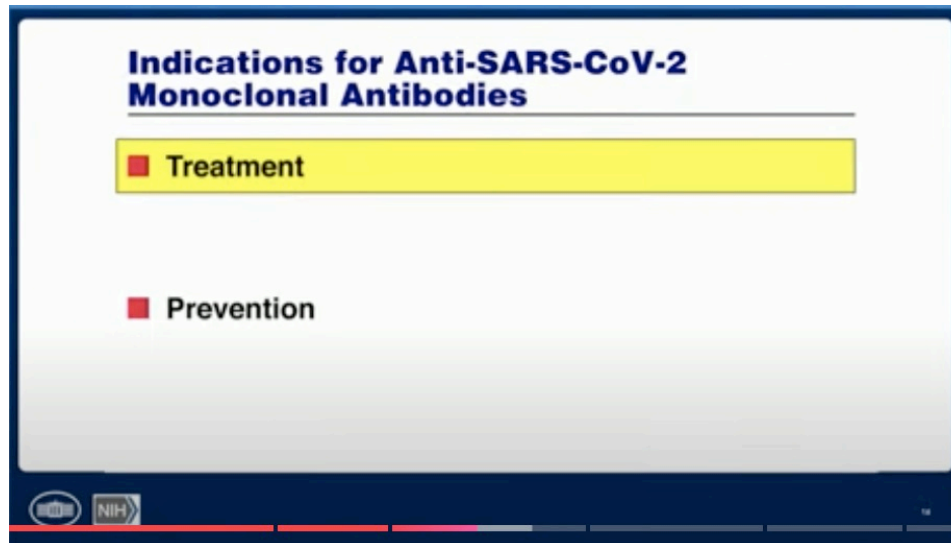
- EUAs for adults and children 12 years and older who weigh at least 88 pounds (40 kg)
 - Bamlanivimab plus etesevimab – Lilly
 - Casirivimab plus imdevimab (REGEN-COV™) – Regeneron
 - Sotrovimab (formerly VIR-7831) – GSK and Vir
- Each of these products targets the spike protein of SARS-CoV-2



So let's look at what we have. We have three anti-SARS-CoV-2 monoclonal antibody products that have currently had emergency use authorization from the FDA; and the EUAs are for adults and children (12 years of age and older who weigh at least 88 lbs.). There are three of them: there's the Lilly product: Bamlanivimab

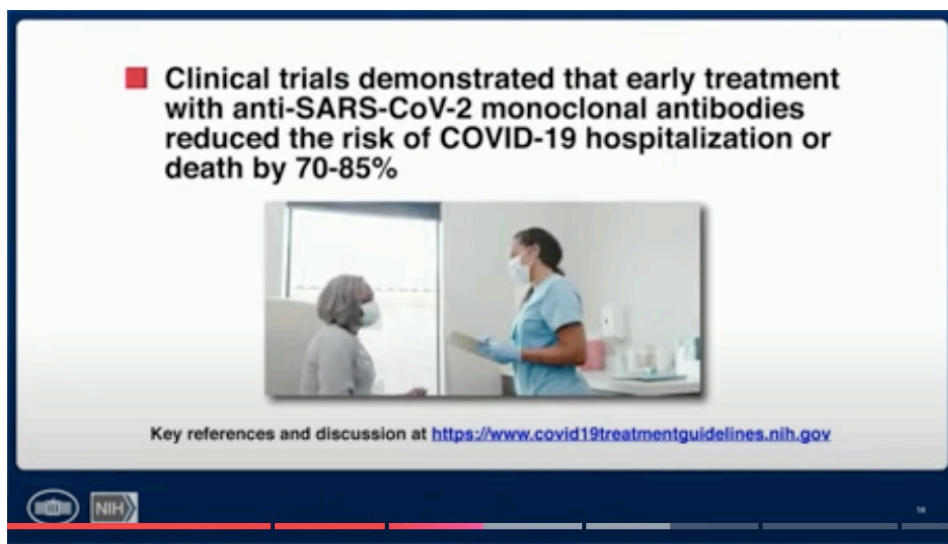
plus etesevimab; there is the Regeneron product referred to as REGEN-COV™; and then there is the GSK and Vir product. Each of these products targets the spike protein of SARS-CoV-2.

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So you can do an indication for these antibodies that are twofold: The first is to treat infection with SARS-CoV-2.

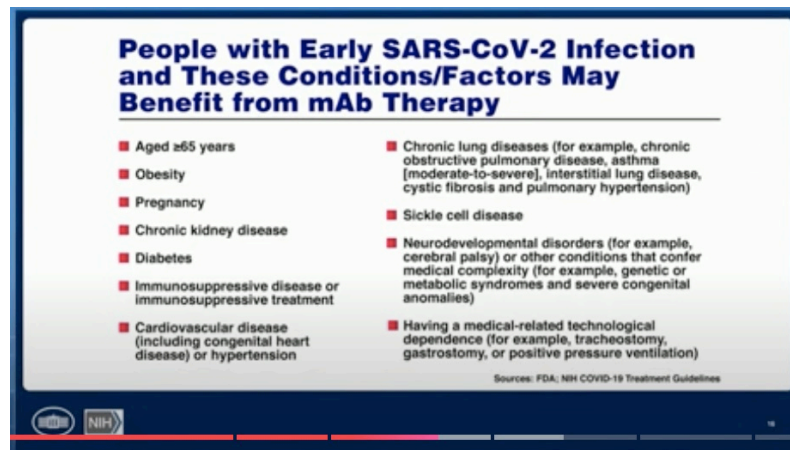
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And in this regard, clinical trials have demonstrated that early treatment with anti SARS-CoV-2 monoclonal antibodies can reduce the risk of COVID-19 hospitalization or death by 70 to 85%. It is important to emphasize that this must be done early in infection and not

wait, of course, until a person is sick enough to be hospitalized. That's when you get the best effect; and, again, being an underutilized intervention, we want people out there including physicians as well as potential patients to realize the advantage of this very effective way of treating early infection.

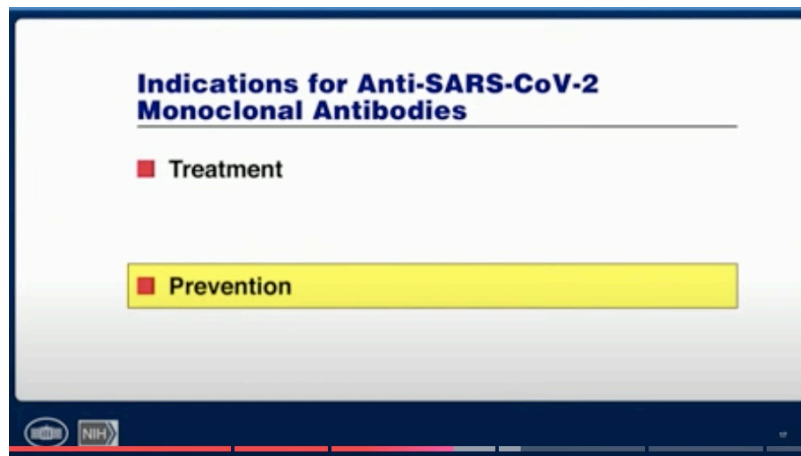
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Now, if you look at the people who should benefit from this, this is a list from the FDA and the NIH treatment guidelines about all of the people who may have significant benefit from this type of therapy if given early in their infection. I'm not going to go through each and every one of them but as you can see there are a number of conditions on this slide that

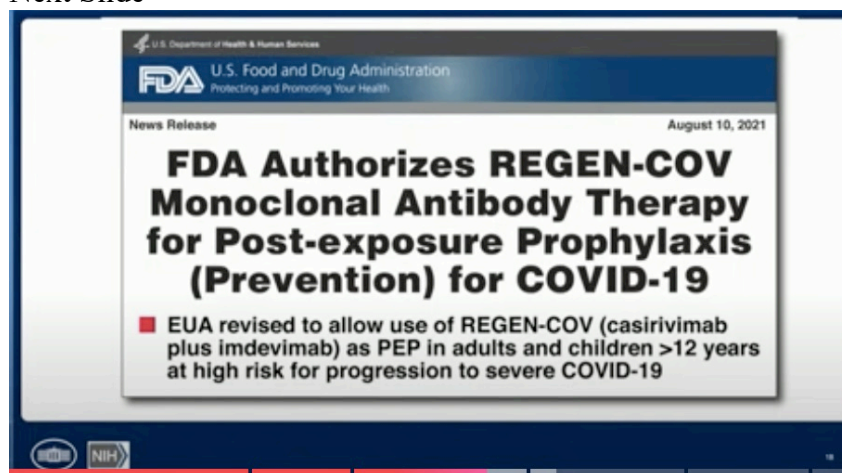
could benefit from the monoclonal antibody treatment after infection.

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But there's also the benefit of prevention using monoclonal antibodies.

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And we know now that the FDA just a couple of weeks ago authorized the Regeneron monoclonal antibody for post exposure prophylaxis—namely, for the prevention of COVID-19 after someone has been exposed to a documented case of SARS-CoV-2. And even now--and I won't show the data because of lack of time--there are now studies

in pre-exposure prophylaxis as well as other studies in treatment. So I'll have on the last slide,

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the treatment guidelines panel we can give you all the information; and it's accessible on the website down here; and for physicians, patients, and others who want to know how you can get monoclonal antibodies administered, this is the call center and this is the online way to approach it. So the bottom line is this is a very effective

intervention for COVID-19. It is underutilized, and we recommend strongly that we utilize this to its fullest.

September 2, 2021, Dr. Fauci slide show on vaccine boosters within the “**LIVE: White House Covid-19 Response Team and public health officials hold briefing — 9/2/2021**”

<https://www.youtube.com/watch?v=ptF6y5ZlglI>

Transcript 6: *The following is a transcript of an interview with Dr. Anthony Fauci, chief medical adviser to President Biden, that aired on Sunday, November 28, 2021, on "Face the Nation."*

MARGARET BRENNAN: Dr. Fauci, thank you very much for making time.

DR. ANTHONY FAUCI: Thank you for having me. Good to be with you.

MARGARET BRENNAN: It's been an incredible past two years. There's a lot to unpack and I want to kind of start off with where we are in this moment right now. We're seeing cases increase once again. Are we in a fifth wave?

DR. FAUCI: Well, we certainly have the potential to go into a fifth wave. And the fifth wave, or the magnitude of any increase, if you want to call it that it will turn into a wave, will really be dependent upon what we do in the next few weeks to a couple of months. For example, we have now about 62 million people in the country who are eligible to be vaccinated, who have not yet gotten vaccinated. Superimpose upon that, the fact that, unquestionably, the people who got vaccinated six, seven, eight, nine, 10 months ago, we're starting to see an understandable diminution in the level of immunity. It's called waning immunity, and it was seen more emphatically in other countries before we saw it here. For example, Israel, which is usually about a month or a month and a half ahead of us temporally with regard to the dynamics of the outbreak, the administration of vaccines and most recently, boosters. So now we know that although the vaccines are very effective and the data that you look at are incontrovertible, that if you compare unvaccinated with vaccinated, infections, hospitalizations, deaths, dramatically multi multifold more in those who are unvaccinated. However, given the waning of immunity, right now boosters are going to be very important. A third shot for those who got the two mRNAs and another additional shot for those who got the J&J. If we have a combination of getting as many people as we can get vaccinated as possible who have not yet gotten vaccinated, add on to it the children who are now eligible, the five to 11, there's twenty eight million of those, and getting the many, many people now, 70% of the entire population of adults has been vaccinated- about 80% has been vaccinated. If we do that successfully in a very intensive way, we can mitigate any increase because if you look at what's happening right now, as you and I are speaking, we're starting to see an uptick that had plateaued at around 70, 75,000 a day. Now it's starting to go up--

MARGARET BRENNAN: --to 80,000--

DR. FAUCI: --yeah, to 80. So if we now do what I'm talking about in an intense way, we may be able to blunt that. If we don't do it successfully, it is certainly conceivable and maybe likely that we will see another bit of a surge. How bad it gets is dependent upon us and how we mitigate.

[WATCH MORE Deaf school captures national attention for football skill](#)

MARGARET BRENNAN: You said in the past that you would like to get under 10,000 infections a day in order to sort of live with COVID.

DR. FAUCI: Right, yeah. You know--

MARGARET BRENNAN: --We're at 80,000. How do you get all the way down there? Is that even realistic?

DR. FAUCI: Yeah, I believe it is. Now MARGARET, I believe it is because there's no doubt there's one thing we know for sure: that 70 to 80,000 a day is an unacceptable level. I mean, we've heard people say, understandably, they're trying to look for a metric to give to the public that we're going to have to start living with COVID. I believe that's the case because I don't think we're going to eradicate it. We've only eradicated one infection of mankind, and that's smallpox. I don't think we're even going to eliminate it. The way you've eliminated polio from the United States, you've eliminated malaria, which was, you know, decades and decades ago. We had malaria right here in Washington, D.C. We've eliminated measles because we have a very, very, very intensive vaccine campaign that did that. So we're looking at control. So control has a pretty wide bracket. You don't want to control at 70 to 80,000. I have empirically said I would like to see it get below 10,000, but maybe even lower than that. Because if you have a smoldering amount of infection in society, that's 20, 30, 40,000 infections, what happens is that as immunity wanes among people, even the vaccinated people secondarily become more at risk. If you lower the level of infection so low that it doesn't give the virus the opportunity to either seek out the very vulnerable, or those who's never been vaccinated, and the somewhat vulnerable, those whose immunity has waned down to a certain level. So that's the reason why we have multiple moving parts. We'd like to be very arithmetic about it. This is the amount we need. This is the time we're going to do it. But when you have these moving parts, the best way you can get to where you want to go is to just say we're going to vaccinate as many people as we can, we're going to get as many people boosted as we can, and we're going to get that level down. And I think that's going to have to be as low as less than 10,000.

MARGARET BRENNAN: But you've been talking about all the problems you have there with convincing these people who are really dug-in and anti-vaccine. Is it really realistic that we have to get to 85% of the population, which is what you've said in the past, in order to sort of have herd immunity? I mean, it seems almost impossible to get there.

DR. FAUCI: Let me get to that number, MARGARET, because it really is important. We have to be very humble about it. We don't know what that number is. And the reason is the number is a moving target. Because if you get someone who's vaccinated and he wanes down and gets below a certain level, I don't know whether you can count that as a full protected person, which is the reason why it's a combination not only of getting the total population vaccinated as a primary, but also getting people boosted. And that's what I mean by a moving target. I've always said, and I hope we can clarify it, that measles, we know that the number of people to be vaccinated is over 90%. And the reason we know it, because when you go over 90, you don't see any measles in the community. When you have pockets of sometimes isolated communities where it goes down into the 80s or so, that's when you get the kind of measles outbreaks. So we know, by almost trial and error, what the level of vaccination needs to be to get herd immunity, which as a concept means there's no virus going around. Everything is protected. You should call it more community immunity as opposed to herd immunity. We haven't gotten there yet with COVID, so we don't really know what that number is.

MARGARET BRENNAN: So what you're describing is never really having control, necessarily, of COVID, but learning to what? Get boosted every six to eight months?

DR. FAUCI: Great question. And that's what we don't know. And the only way- the important part when you're dealing with a unique, never-before-experienced outbreak of a new virus, that sometimes you can extrapolate what you know about other viruses because there are some commonalities, but sometimes you have to realize that this may be very unique. So for example, if we get a third shot with an mRNA, it is conceivable that there will be, based on immunological memory of B cells and T cells, the different types of cells that protect you, that you would get enough of what we call maturation. Affinity maturation means get those cells really, really trained to be able to powerfully block significant disease. It may not block getting a little sniffle, but it'll block you from getting significant disease. It is conceivable that when we get that extra boost, that will make the durability go well beyond six months and even longer. Or it may be that we will have to boost people intermittently the way we do it with influenza. Right now, we do not know definitively what that course is going to be. Whether it's going to be a three shot and you're done or three shots and then every once in a while you have to reboost. We'll have to see how things roll out. Otherwise, we just can't say something and guess about it.

MARGARET BRENNAN: Why isn't the CDC tracking breakthrough infections? Wouldn't you be able to better answer that question if you knew?

DR. FAUCI: Yeah, I mean, yes, in many respects, they are. One of the things that--

MARGARET BRENNAN: --Among health care workers.

DR. FAUCI: Yeah, yeah, we need to do a lot of things and the things that we certainly need to do, and we've been discussing this as recently as yesterday, that we really need to find out when you do boost an individual, how long does that immunity last, both from a laboratory standpoint and from a protection standpoint? So the one thing we want to make sure, now that we're getting full blown into the booster phase, we've got to make sure we know what that means from a clinical standpoint.

MARGARET BRENNAN: Because the public hears you cite information out of Israel, out of a foreign country. Why don't we have that data collection happening here now?

DR. FAUCI: We should have it. We should have it.

MARGARET BRENNAN: Why don't we?

DR. FAUCI: I can't--

MARGARET BRENNAN: Why did- why did the United States decide not to track those breakthrough infections?

DR. FAUCI: Well, it's a very complicated indication- excuse me. It's a very complicated situation. And often the public doesn't hear yet in time things that are being collected. So there's a lot of data, clearly a lot of data, that's being collected by the CDC that people don't know about yet. So we need to make sure in real time we get that data out. Historically, when you're not in a pandemic, you can collect data, you can analyze it, you could talk about it and then you could look back and say this is what we've done. But when you're dealing with a pandemic, you've got to

get that out in real time so your policies can be dictated by data that occurred relatively recently, not data that occurred four or five months ago.

MARGARET BRENNAN: That's the criticism that they're too academic.

DR. FAUCI: Right, yes.

MARGARET BRENNAN: But is there data being collected now in the United States about breakthrough infections that the public doesn't know about?

DR. FAUCI: Yes, yes. Yes. The CDC is collecting data, yes.

MARGARET BRENNAN: Beyond just health care workers, everyday people. You have an idea of what's happening with breakthrough infections?

DR. FAUCI: I don't have the data for you right now, that's obviously- we'll have to get the CDC to get us that.

MARGARET BRENNAN: Let me ask you about how people should be handling the data they may have now, with their kids in particular. The Education Secretary recently told me there should be no need for remote or hybrid learning. OK. But then there are a lot of really confused parents out there.

DR. FAUCI: Right.

MARGARET BRENNAN: Each school seems to be handling this differently in terms of masking and not masking, or when they alert parents and the like. What's the most responsible thing for parents to do if they know they're sending their child into a classroom and someone in that room tests positive?

DR. FAUCI: Yeah, there are a lot of options about that. The one thing you don't want to do, and again, this is the CDC guidelines. This is the kind of things that they have been analyzing and trying to get the best approach. You know, there's the test to stay. In other words, if you test and you're negative, you don't have to go out and get quarantine. The idea about when you get an outbreak in a class of two, to then immobilize essentially, the class is functionally very, very difficult to get a good academic year with some continuity about that. And that's the reason why we need to do several things all at once. One, you want to surround the children with adults who are completely vaccinated. Number two, you want to vaccinate the adolescents that we already have been vaccinating for some time. Vaccinate the five to 11 year old. And when there is a case in the school, then you really got to do something about--

MARGARET BRENNAN: Sometimes parents don't even know if there's a case in the school.

DR. FAUCI: I know that and it's- MARGARET, it's got to be articulated much more clearly, so that people know exactly and there's no ambiguity about that. When you don't know what the situation is and you have community spread around, that's the reason why the CDC still recommends masking for the children in school.

MARGARET BRENNAN: The CDC guidelines, they're pretty convoluted about it. It says get tested immediately and quarantine if you've been exposed- this is for children. For a period of 14 days, unless you receive instructions from the school official or a public health official. It really kind of leaves it up to a lot of interpretation there.

DR. FAUCI: I know. And I believe that has to change, to make it more- You know, my approach has always been to be very explicit and then repeat what you said.

MARGARET BRENNAN: Right. So- so for parents now that have partially vaccinated children, some unvaccinated children, I mean, are all of these guidelines just also going to be a moving target?

DR. FAUCI: Right. No, I hope the guidelines- I think the data will change as we get more and more experience, particularly as we get into a situation where you have more people vaccinated and you get boosted. But you have to get the data to be as close to the recommendation as you possibly can. You can't have it be too much lagging because then you're behind the time.

MARGARET BRENNAN: But this is one of those criticisms of how our country responded here. Which is just- maybe it's by virtue of the federal system, but district by district, state by state, different things. And then they look for you for unified, "Tell me what to do. Just tell me what to do with my kids."

DR. FAUCI: Yes.

MARGARET BRENNAN: Clarity.

DR. FAUCI: Yeah, I mean, but the clarity when it comes to the situation of the public health, we really need to- and I think they are very likely doing much, much better than what the public thinks they are- is to get the CDC to be very clear, to be very, very sharp about what a recommendation is. And when you don't know what the data- I mean,

when there's no data to make that to, then just give a recommendation based on best judgment, if you want to call it that.

MARGARET BRENNAN: And when you say lack of data, this has- this has been a criticism throughout. That there's just not enough information being collected in this country. Not enough surveillance being done. Is that still the case in your view?

DR. FAUCI: We do- we need to do more. No doubt about it. No doubt about it. We need to do more surveillance and we need to do more testing.

MARGARET BRENNAN: Would we have to worry about vaccinating babies, toddlers, if adults were vaccinated at a higher rate? I mean, very young children still won't have a vaccine well into 2022, according to Pfizer.

DR. FAUCI: Well, I believe it's going to be in the first quarter of 2022. I would hope it would be in the first quarter because the studies are being done right now on children from two to five and then from six months to two years. And now they may take longer because the younger you get, the more obviously vulnerable. Children are vulnerable. You got to be extra, especially careful about safety. I don't think there's going to be an issue with efficacy. There's no reason to believe why it will not be efficacious and ultimately effective in the children. But when you're dealing with children, it's a very sensitive area. And that's the reason why I may take a little bit longer. But I would hope by the time we get into the first quarter of 2022, we'll be able to do that. You know, one of the things that people should appreciate is that we are in a very stressful, unique and complicated situation with COVID 19. But when we look back on this, it's going to settle into something that will ultimately be a policy that's been tried, true and tested. We vaccinate children way down to lower age for diseases that have much less morbidity and mortality than COVID-19. So that's what I say when people say, "Are you sure you want to be vaccinating the children?" Yeah, we do want to be vaccinating the children because we want to vaccinate and protect everyone in society, including children.

MARGARET BRENNAN: But the CDC often takes years before they give that recommendation for pediatric vaccines. Do you think it'll move faster?

DR. FAUCI: Yes, it will.

MARGARET BRENNAN: So next year, kid goes into the classroom. Will it be required, do you think?

DR. FAUCI: I don't know if it's going to be required, but I can tell you, I have always been- I mean, I'm an infectious disease person. I'm a public health person. I would push for getting people who are vulnerable, and children are vulnerable, as quickly and as efficiently as possible.

MARGARET BRENNAN: So when do we get to pull back the public health restrictions for kids? Is it until the toddlers get vaccinated?

DR. FAUCI: No, I think that you're going to see likely a gradual pulling back when you get- You have to put the dynamics of the outbreak in a community into the mix of your decision making. You're going to have children vaccinated. You'll have teachers vaccinated. When the community level goes down- I mean, being in a- in a region, a state, a city or a county in which you are red hot by the color code, versus red, orange, yellow, green, et cetera. If you're in a red hot area, you're not going to want to pull back on masking or pull back on any of the mitigation. If X number of months from now, you have a very high proportion of children vaccinated and you are in an area with a level where I call the dynamics of infection is very low, I would be almost certain that you're going to see a significant diminution in the mitigations, such as masks and things like that.

MARGARET BRENNAN: Mm-Hmm. It's just such a moving target for people all the time, and they say, How do I know my community infection level? How do I know what's red? What's green? What's OK?

DR. FAUCI: Yeah, I know. Easiest way to say click on the CDC website and you can- you can figure it out in a second. But not everybody has access to that, and not everybody knows how to do that. So it's going to be a combination of those who can access that online information, as well as getting out there would a lot of PSAs. I mean, the Community Public Health Service, that's one of the things that I've been talking about for some time now. When you talk about what the successes and what the vulnerabilities of our response have been to this, I divided up into two groups: scientifically preparedness and response and public health preparedness and response. Fortunately for us, the scientific preparedness and response has been unprecedentedly good, if not magnificent. And to be able to get a vaccine from the time you get the sequence of the virus, to get it a successful, highly effective and safe vaccine in the arms of individuals within 11 months has never even been imagined, much less done. So the science came through, the science came through. The public health is different. We thought we had a good system. We found out that our public health infrastructure at the local level was just extraordinarily outdated in so many respects.

Personnel were leaving. People were using fax machines instead of computer online things. If you want to have a tracking of an outbreak or responding to an outbreak, getting messages out to the community, knowing whether you live in a community that's a yellow, an orange or a red so that everybody in the community knows, that's something we did not have early on.

MARGARET BRENNAN: And we still don't have a national surveillance system that from the local level up--

DR. FAUCI: --Not to the level that I was built to be appropriate. Right--

MARGARET BRENNAN: --is built out. So you just brought us to one of the chief public failures as diagnosed by other doctors, and I want- I want to tick through some of these--

DR. FAUCI: --Alright--

MARGARET BRENNAN: --to see if you agree--

DR. FAUCI: --Sure--

MARGARET BRENNAN: --with some of the criticisms of the public health response. The U.S. didn't have a national surveillance system, testing was inadequate and there was a lack of data.

DR. FAUCI: Right.

MARGARET BRENNAN: You agree with that.

DR. FAUCI: Yes.

MARGARET BRENNAN: It was a deadly mistake by the CDC to try to use the flu as a model, according to Dr. Deborah Birx. It meant doctors were looking for spread in the wrong places and did not recognize the possibility of asymptomatic spread. Was that the chief, early on?

DR. FAUCI: Well, you know, I think that some of what you said is correct. The idea about not recognizing that it was spread in a very efficient way, in an asymptomatic situation, was really a problem. Because what it did- it did not allow a testing of the asymptomatic individuals, which should have been done right from the get go.

MARGARET BRENNAN: People were walking through TSA, getting their temperatures, and that meant nothing.

DR. FAUCI: Right. Well, I always said that that was meaningless because I've been having my temperature taken and sometimes it's 32, which means I should be dead.

MARGARET BRENNAN: But it's the theater of public safety rather than the reality of it.

DR. FAUCI: Yes, yes. I agree. I agree. I mean, clearly we needed to test people who are asymptomatic. No doubt about that. That would have changed a lot of things.

MARGARET BRENNAN: And the flu model being used? Why was it used?

DR. FAUCI: You know, I can't explain that. That's not what I do. I'm sorry I have to tell you that.

MARGARET BRENNAN: Wasn't as discussed at the- at the COVID task force meetings?

DR. FAUCI: No, it was not. It was not. It was just the CDC would do that and that's the way they looked at respiratory diseases. And it took a while to figure out that this is really, really different from flu, in many respects.

MARGARET BRENNAN: Mm-Hmm. When did you realize that?

DR. FAUCI: Well, Debbie Birx and I realize that right, you know, right in the middle of the outbreak. You know, the- 2020, right in the middle of 2020, it was very, very clear. And if you go back over the history of that, we did, I did certainly, said we need to be testing. I remember the words, if you go back on some of the statements I made at some of those White House press conferences, we need to flood the system with testing, is what I would say very often, flood the system with testing. Which means not just somebody who shows up with symptoms. Mm-Hmm.

MARGARET BRENNAN: But I mean, we looked back at statements and in February of 2020, very early on there, you were still saying it's certainly a possibility, but it's extraordinarily unlikely that COVID was spreading in the U.S.

DR. FAUCI: Right, and that's because we didn't know it at the time.

MARGARET BRENNAN: Why did you have that blind spot?

DR. FAUCI: Well, it wasn't a blind spot because we didn't- we weren't testing. That was the point. What we were seeing is that the flu model is you look at symptomatic disease, ILIs, flu like illnesses, you know, those were the ones, influenza like illnesses. And influenza like illnesses are not noticed unless you get an influenza like symptom.

So the model of using a flu model was never able to get applied until it was clear that it should have been not the ILI, but that the asymptomatic model that when you have a disease in which you have 30 to 40% of the people who get infected have never- no symptoms, then you see transmissibility. 50 to 60% of the transmissibilities occur from someone who has no symptoms, who either never will get symptoms or is in the pre-symptomatic phase. That was unprecedented in respiratory illness. So I guess you could say, well, you should have known that. The CDC should have known that. Well, maybe they should have known it after it happened for a bit, but they couldn't have known it from day one. You could not have known that from day one. But it should not have taken so long to figure out that, in fact, we have a substantial amount of transmission that's asymptomatic, which should trigger why you should be testing asymptomatic people. And getting back from things that have been brought up by historians now, because it was a year ago, when that came out of said only testing people with symptoms, Debbie Birx was against that and I was against that. It was very, very clear that we should be testing asymptomatic people.

MARGARET BRENNAN: It also brings us to why people should have been wearing masks earlier. They didn't know that they were spreading it.

DR. FAUCI: Exactly. And that's the reason why back in January and February, we're saying we're not so sure you really need masks because we didn't realize at the time that there was being asymptomatic spread. That was one of the real reasons. As soon as that became clear, there was no doubt you should be wearing a mask.

MARGARET BRENNAN: Matt Pottinger, the former deputy national security adviser, brought that up, and he told us that was one of the most costly mistakes. And he brought it up in the context of- he said he was talking to doctors he knew in Asia who were telling him things that the CDC was saying, you're wrong, that the CDC was telling him he didn't know what he was talking about. Though he was talking to people on the ground who were telling him firsthand, this is how the virus was spreading.

DR. FAUCI: Right.

MARGARET BRENNAN: Was the masks the costliest mistake? And where do you rank that the lack of informing the public earlier on to wear them?

DR. FAUCI: Well, it was not only the masks. It was not realizing that we had an insidious enemy in the virus that was lurking below the radar screen. And it's not just a question of wearing a mask, which should have been done at the time had we known that. It was the realization that in crowded places, poor ventilation, congregating together. When you have an infection that 50 to 60% of it is transmitted by an asymptomatic person, a lot of things change, not just masks. Masks are clearly one of the big ones. I mean, I get asked that question all the time about why not mask in the beginning. It was not an appreciation. First of all, besides the fact that we didn't realize masks outside of the hospital setting work. We didn't know that. It was said- it was said the data shows it works in the hospital, but we don't know--

MARGARET BRENNAN: Matt Pottinger was saying he was in the White House telling doctors that you need to wear them. Look at what's happened in Asia previously and wearing masks.

DR. FAUCI: Right, right. And the fact is, the Asians wear masks is a very important part- long yet- long after COVID leaves us, the Asians are going to be wearing masks.

MARGARET BRENNAN: Will we be wearing masks?

DR. FAUCI: I think we might. I think people are going to realize that one of the things that was noticed, very clearly now, is that when you were wearing a mask, when everybody finally realized it was important to wear a mask, that influenza was sort of off the map. I mean, we didn't have hardly any influenza last winter. The Australians didn't have any influenza. So it was very clear, that something that was not fully appreciated. It was somehow dogma, which it was assumed that masks in a hospital setting work, but there's no evidence that they work outside of the hospital setting. And then when they did better analysis, it became clear that masks do work outside of the hospital setting. There was a feeling that, well, if we wear masks, we're going to take away from the masks that are needed by the people who were in the hospitals.

MARGARET BRENNAN: Because there wasn't an adequate stockpile.

DR. FAUCI: There wasn't an adequate stockpile. So that's where it was- then not a push for people to wear masks. And then the thing that was the real clincher, for sure, was the realization that you may be standing next to somebody talking to them, they have no symptoms and then they're infecting you right now. This idea, which was getting back to the incorrect flu model, which was clearly originally extrapolated to COVID, now it's clear it is not the right model, is that in a flu season, there's a very, very brief window before you get symptoms that you could

transmit it. But you don't have people who go through the entire flu and- and- and- and don't get symptoms. So COVID is very different from flu in many respects.

MARGARET BRENNAN: I point some of these specific things out because they don't- they're not political. These were public health mistakes.

DR. FAUCI: Right.

MARGARET BRENNAN: That's almost scarier.

DR. FAUCI: Well, you know, I think to- to defend the CDC, if I could for a moment, is that one can say something is a mistake because, you know now data now that you didn't know then. So technically it really is a mistake. But if you had--

MARGARET BRENNAN: But then- but then if you look at the news reports, I mean, you look at doctors in China, in hospital wards, in hazmat suits.

DR. FAUCI: Right.

MARGARET BRENNAN: And we're talking about putting a mask on your face as being ridiculous at the time. I mean, it just in hindsight, it looks so--

DR. FAUCI: --but--

MARGARET BRENNAN: --obvious, but we were not up to the challenge here in getting ahead with such cutting edge medical care in this country. It's kind of shocking, isn't it?

DR. FAUCI: Well, you're right in saying that, but let's get back to the hazmat suit because I'd like to respectfully correct you for a moment.

MARGARET BRENNAN: Go ahead.

DR. FAUCI: Is that hazmat suits were used by people who were taking care of sick individuals.

MARGARET BRENNAN: Mm-Hmm.

DR. FAUCI: You didn't see too many people in China wearing hazmat suits walking down the street. They were wearing masks--

MARGARET BRENNAN: --No, in hospitals--

DR. FAUCI: --yeah, in hospitals--

MARGARET BRENNAN: --and our doctors didn't have adequate care when they needed it.

DR. FAUCI: In the very beginning, we didn't have- It's not that we didn't realize you should wear them. It was that we didn't have enough PPE right in the beginning.

MARGARET BRENNAN: But my point was, isn't that a warning--

DR. FAUCI: --Yeah. Yeah--

MARGARET BRENNAN: --when you see it?

DR. FAUCI: Yeah, like I said when I told you a moment ago. It was the scientific approach, preparedness and response, and the public health preparedness and response. I find it interesting that I'm here responsible for this and trying to defend this.

MARGARET BRENNAN: No, I think you're just- you're America's doctor, Dr. Fauci. So everyone looks to you to explain it all.

DR. FAUCI: That's true, and I try to explain it to the best of my ability. But there are some things that I can't defend because I'm not responsible for them. Maybe I would have done them differently if I were responsible for them. But if I'm not responsible for them, you want to talk about vaccines. That's what I did.

MARGARET BRENNAN: **But just to button that up. Why aren't we having a national conversation about what went wrong? I mean, apart from this room right now, why isn't there a 9/11 type commission?**

DR. FAUCI: **Yeah, I think what's going to happen is that you are going to see that for sure, MARGARET. I think the lack of doing that now is because you're focusing on getting this thing under control. I would be astounded if we didn't have a very serious look at what went right, what went wrong, from a public health standpoint, from a local standpoint, from a global standpoint. I don't think that the public should imagine that this is going to go through with already 760,000 Americans dying and 40 plus million at least being**

infected, close to six million people globally dying. And we're not going to look back at this and tear it apart, examine it, do an autopsy on it and try and figure out. So people should not think that that's not going to happen. It's not happening now because everybody's focusing on getting this thing under control.

MARGARET BRENNAN: But you want one?

DR. FAUCI: Oh, I absolutely want one.

MARGARET BRENNAN: And do you think the administration will? Well, when will we see that?

DR. FAUCI: Yeah. I think once we get it on the much better control, you're going to start seeing a real close examination of that.

MARGARET BRENNAN: You- well, in our examination of that, you were quoted as saying it was the worst possible decision for the Trump administration to have left things up to the states.

DR. FAUCI: Yeah.

MARGARET BRENNAN: Where do you rank that?

DR. FAUCI: I rank that right there, maybe a little bit below some of the things you are talking about, but way up there. Because my- as a scientist and a public health person, you know, people always ask if you had the magic wand and did things exactly the way you wanted, what it would be? One of them would be if ever, if ever there was a situation where you needed a synergistic uniform, well-thought-out approach is when you're dealing with a common enemy of a virus that is a global pandemic, the likes of which we haven't seen in 100 years, to be able to say if I don't really want to do this because I want, you know, my own opinion of what it's going to be with this state versus this state versus this state. To me, that's one of the antitheses of public health. We know exactly what needs to be done. We know you've got to get vaccinated. How can you possibly have a situation where one state says, I'm sorry and you shouldn't be wearing a mask? In fact, you have executive orders saying you shouldn't be wearing a mask.

MARGARET BRENNAN: Florida.

DR. FAUCI: You have another state that does not want to get vaccinated because they think it's a political statement to get vaccinated or not. I mean, we've had and I've said it many times, and I'll say for you, the divisiveness in this country to me is the biggest mistake that supersedes everything that we're talking about, supersedes the mask situation, supersedes everything, have a public health catastrophe and you have divisiveness that is pulling away from doing the right thing to get the outbreak under control. I mean, when we look back historically and look back at this and said we had this devastating plague out there that were killing hundreds of thousands of Americans, and we're having public health principles being decided on the basis of political ideology. I mean, when I give my history of it, that's going to be the number one mistake that supersedes all the other things that we're talking about.

MARGARET BRENNAN: Public health is often politicized. I mean, you know that so well, from your experience with AIDS, what was the chief lesson you brought into dealing with COVID from that experience with AIDS?

DR. FAUCI: With AIDS? Well, the one thing that- well they were more than one with HIV AIDS is never underestimate infectious disease outbreak because it can be insidious the way AIDS was under the radar screen. And then you find out, you know, 40 years later, it's killed 37 million people, 77 million people have gotten infected. You learn also to pay attention to what's going on in the community. And that's the major lesson I learned. I listened to the people and I wanted to find out what it is that was going on with them. How were they getting infected? Why were they getting infected? What was going on with the circumstances? That's how you really get your arms around an outbreak. You don't do it from above and dictate down. You go into the community and you find out maybe some of those lessons about finding out what's going on in the community with infection would have done us a little bit better.

MARGARET BRENNAN: Was that happening at all in China when this first appeared going back to the fall of 2019?

DR. FAUCI: You know, it was very tough what was going on in China. You know, it's kind of opaque. Clearly there was infection that was percolating, you know, as early as November, maybe even earlier. And then it was the same sort of thing, you know, back then, you had an infection that emerged almost certainly out of an animal reservoir to a- I mean, the bats there all have viruses that when you- the more you study bats there, the more you see how close some of the viruses are to SARS-CoV-2. Clearly, SARS-CoV-1 was a bat to a civet cat to a human. MERS was a bat to a camel to a human. In the beginning, when it first came out, it was, I remember, very, very clearly. It was the very, very end of December, the beginning of January. There was this outbreak in China. Of some unusual cases that

was felt to be well, it looks just like SARS-CoV-1, and SARS-CoV-1 was one that was not spread very readily from human to human. It was spread almost all by symptomatic people, hence the transmissions that occurred in hospital and doctor's waiting rooms while people were coughing and sneezing. So it was assumed in the beginning, well, this is the coronavirus. We've just sequenced it on January 10th. We know what the sequence is. Why it- isn't it just assumed that it's SARS-CoV-1, which means it doesn't transmit very well and it's going to get controlled by public health measures, which is exactly what happened with SARS-CoV-1. Then you find out that even though it's SARS-CoV-2, it is a very, very different virus than SARS-CoV-1 because A, it is transmitted spectacularly efficiently from person to person-

MARGARET BRENNAN: Why?

DR. FAUCI: And B, most of it is a- 40 to 50 to 60 percent is asymptomatic.

MARGARET BRENNAN: Why is it so efficient? I've heard so many virologists point to that that it was uniquely adapted to be just horrible in a human body. How did it get that efficient?

DR. FAUCI: Well, it evolves in animals, it evolves in humans, and it could just, you know, sometimes viruses jump into humans and they take off and run right away.

MARGARET BRENNAN: But we don't know what went between the bat and the human. There was something in between?

DR. FAUCI: It was very likely in a host- what the Chinese did, I don't have firsthand knowledge of that, but the people who were reporting it, who investigated what they did is they cleaned out the markets as soon as it turned out that it was clear that there were clusters coming from the market. Which, you know, in typical fashion, I think trying to make sure that things don't get pointed to them, they probably got rid of the animals that were the intermediary hosts there. And that's the reason why it's very important to continue to get the cooperation of the Chinese in allowing surveillance of the animals that ultimately go into the wet markets, the civet cats, the raccoon dogs and all those other things that clearly the- this virus is a very promiscuous virus in the sense that it can infect animals. Animals can infect humans. There are animals out there, big cats, there are animals in the environment that are getting infected with SARS-CoV-2. It's a very highly infective- as long as you have that receptor for the virus, it'll infect you. So that's what makes it- its capability of binding so well to the receptors in the body.

MARGARET BRENNAN: But Beijing acknowledges now that they don't think it originated in that market.

DR. FAUCI: Well, it may not have originated in the market, but it certainly could have, I mean, I don't think that they admitted that it didn't originate in the market. I think they're saying they don't know how it originated.

MARGARET BRENNAN: Well, there were clusters that may have been picked up and transmitted,--

DR. FAUCI: Yeah.

MARGARET BRENNAN: --as I understand it, through the market,--

DR. FAUCI: Yeah.

MARGARET BRENNAN: --the place of origin was not within the market itself.

DR. FAUCI: I don't think you could say that. I don't think you can say that. I think you could say we don't know how and where it originated. There were wet markets in Wuhan that are ample opportunity for a virus to jump from an animal that gets brought in from all parts of China that are very closely related physically to bat enclaves in caves and come to the market. So I don't think anyone can say that it didn't come from here or it did come from here.

MARGARET BRENNAN: So it was the end of 2019 when the World Health Organization was first alerted about the strange pneumonia. Doctors, as you just said, had been tracking back to the fall, possibly as early as October. When was the first time that you heard that there was something, some strange pneumonia?

DR. FAUCI: I think it was the very last day it may have been Dec 31 or the 30th or 1st of Jan.

MARGARET BRENNAN: When they informed the World Health Organization?

DR. FAUCI: Yeah, I mean, I got- I got a call from Bob Redfield who said, you know, I just heard from colleagues in China that there's an unusual pneumonia among people that has been detected. So we just got to stay heads up for that. And then a few days later, I think it was Jan 9th, or 10th the sequence came out. I got- as soon as I heard there was a new pneumonia, I said, well, a new pneumonia, Wuhan, wet market almost certainly it's going to be a coronavirus. We all thought it would be similar to SARS-CoV-1, and that's when I got my team organized immediately and said as soon as we get that sequence of what it is, let's go after that vaccine, let's plug it into MRNA. We were already collaborating with Moderna with MRNA and let's do it. And it was rocket speed. I mean,

we found out on the 10th of January of what the sequence was. About five or six days later we were starting with the vaccine development with Moderna. Sixty-five days later, we did a phase one trial, and multiple months later, we knew we had a safe and effective vaccine.

MARGARET BRENNAN: And- and that's incredible speed that you were already there, but it was despite the lack of information being shared. You you mentioned SARS,--

DR. FAUCI: Yeah.

MARGARET BRENNAN: the first version of it, you had experienced--

DR. FAUCI: The only- the only-

MARGARET BRENNAN: --Go ahead.

DR. FAUCI: Again, I'm going to get back to what- what I do and my job was to develop a vaccine. So the only information I needed was the sequence of the virus. And when we got that information, I put my team to work to make a vaccine, which was made in unprecedented record time to be a safe and highly effective vaccine. The antigen that's used, the immunogen that is used in virtually all the vaccines, regardless of what the platform is, was developed at the Vaccine Research Center by my scientist in the institute. So that's all I needed was the sequence. I mean, the public health part was handled by the CDC. I just needed the sequence of the virus to make the vaccine.

MARGARET BRENNAN: So the live- live virus samples wouldn't have had a- it made a difference for you.

DR. FAUCI: I didn't need it at all. I just needed the sequence to get a vaccine.

MARGARET BRENNAN: So you knew doctors in China and the head of their CDC as all of this is going on. Bob Redfield, the former head of the CDC, said- and you know the story well. He was called by his Chinese counterpart weeping in January saying this is out of control.

DR. FAUCI: Right?

MARGARET BRENNAN: He maintains, Dr. Redfield, that their CDC was kept in the dark. You know, these doctors, I mean, is that what happened? How did this get so far ahead of the medical community?

DR. FAUCI: I can't- I can't comment because I don't know. Margaret, what went on in China, except that the scientists that I know were communicating with us to the point that we- we have a real problem here. This is bad. We're seeing people getting infected and they're getting really, really very sick. And it's not like flu and it's not like anything else we've seen. That's- that's what we got. I mean, that was the information we got. And then when the Chinese started building, within days, these massive hospital complexes, then it became clear that this is a real problem.

MARGARET BRENNAN: When did the alarm bells go off for you?

DR. FAUCI: Well, they were gradual, it wasn't like one big aha, or alarm bells. It was just a gradual rolling out of new information that every time new information came in, it didn't make matters better. It made matters worse. So for me, my job being to get the vaccine, while we were working on the vaccine, I wasn't sure whether it would be a vaccine that we would never even need or be a vaccine that would be lifesaving for millions the way it turned out to be. So what happened? The evolution and the rolling out of the information. First, It's a coronavirus - good. Is it like SARS-CoV-1? Maybe, maybe not. A week or two later, wait a minute it is transmitted from person to person. It isn't just animal to human. A week later, not only is that person to person, it's pretty efficiently from person to person. Two-three weeks later, you know, there is some transmissibility that's from people without symptoms. And then a month or two later, well, not only is it transmissible without symptoms, but half of the transmissions are from people who don't have symptoms. And that was a period from literally day one into several months into it. And by the time we got months into it, New York was getting hit badly. It was clear, wait a minute, we don't- we didn't know back then what we know now, but every time we get new information, it gets worse and worse and worse. That's how things evolve with the pandemic. You don't know from day one exactly what's going to happen on month six until things evolve, because we've never had that situation or that experience before.

MARGARET BRENNAN: I want to read you something you said back in 2019 when somebody asked you what keeps you up at night? You said, "the thing I'm most concerned about is the emergence of a new virus, the body doesn't have any background experience with very transmissible, highly transmissible person to person, high degree of morbidity and mortality. The thing that worries most of us in the field of public health is a respiratory illness that can spread even before someone is so sick that you want to keep them in bed."

DR. FAUCI: Right.

MARGARET BRENNAN: You were describing COVID.

DR. FAUCI: I was. My- my worst nightmare that I've been asked about multiple times over the last 37 years that I've been directing the institute has come true. And I've- that statement that you read, I must have said that 50 to 100 times to people in the media, people in the scientific community. When they ask me, what do you really worry about? I've said that- in fact, I said that to multiple presidents along the way, going way way back. I've said it to Reagan. I've said that to George H.W. Bush, to George W. Bush, to Clinton, to Obama. I've said it to everyone. My worst nightmare is something that you've just described, and unfortunately, it's happened.

MARGARET BRENNAN: How many times have you thought of that in the past two years? I've- I've warned about this.

DR. FAUCI: Yeah. I mean, I think about it every day, really.

MARGARET BRENNAN: I mean, it's an incredible description of where we are. How do you grade America's response to your nightmare scenario?

DR. FAUCI: Yeah, I grade- as I said, I look at a response as a person who is fundamentally a scientist and a physician and a public health person, indirectly that what I do is I look at preparedness and response in two pillars. One is scientific, and one is public health. I grade scientific, A+. I grade public health. C, B+, B-, C somewhere between B and C. It certainly is not A.

MARGARET BRENNAN: Do you think that there are lessons learned from this that improve the scenario, or are we in a place as a country where we're just not ready to fix ourselves?

DR. FAUCI: Well, we better fix ourselves because going back to what I said, Thirty seven years ago, thirty years ago, twenty years ago, ten years ago, it's going to happen again. We're going to get another pandemic. It might be a blip on the radar screen, a new emergence that doesn't go anywhere or it might be something that explodes like this. But if you look at the history of mankind, we've had plagues before the ability to document them by scientific methods like identifying the agent like a thousand years ago, 2000 years ago. Then we've had outbreaks that have devastated us during times when history could record it, and then we've had outbreaks that have occurred when you could actually document what it is. Now, why do we think in our naivety that this is not going to happen sometime in the future? So I would think it would really be a shame on us if we don't take these lessons that we've painfully learned and make sure that they are lessons that have been learned and not just forgotten and put aside. That's the thing that I hope for.

MARGARET BRENNAN: Sometimes, though, it seems the public thinks that the election changed everything. But what you're describing are some deep institutional problems and things that we really need to have addressed still.

DR. FAUCI: Yeah. Yes, I mean administrations come, administrations go they- they vary in their response. I think right now, currently, the attention that's being paid to this, the effort that's put in to get vaccines distributed. I think this is a good response that's happening right now.

MARGARET BRENNAN: Do you think there need to be tougher regulations for- for labs that deal with contagious- highly contagious viruses?

DR. FAUCI: Well, we did that years ago, we put a three year pause in any of the experiments that would be involving anything that would be dangerous and examined it very carefully, not we, the NIH or the CDC, but outside bodies like the National Academy of Science, the NSABB, multiple workshops to come up with a framework that would guide the kind of work that should be done, the conditions under which should be done, the kinds of things that should not be done. I don't think the public fully realizes that. They hear these words that mean nothing to them, like gain of function. What the heck does that mean? But what they think- People should realize that we are always open in the scientific community to re-examine what we do and how we do it--

MARGARET BRENNAN: And gain- gain of function for people listening is trying to give a virus new, improved abilities.

DR. FAUCI: Right, and- and sometimes it's for a very- not sometimes you always do it and examine it because much of the science that gets done is by modifying things, modifying cells, modifying viruses to be able to study them well enough to prepare you for what will ultimately come. And there are very strict guardrails about that that I don't think the general public fully appreciates. When you have people that can make outlandish statements about things that are just not true.

MARGARET BRENNAN: This is a political football, right?

DR. FAUCI: Oh, it is a total political football, total.

MARGARET BRENNAN: And you take the fire specifically for this.

DR. FAUCI: I do. I do, all the time.

MARGARET BRENNAN: There's a congressional act with your name on it, literally.

DR. FAUCI: Yes, exactly. And it's just a lot of- well, anyway,

MARGARET BRENNAN: Finish the thought.

DR. FAUCI: No- no. There's a lot of politicization of that. And I think there's a lot of misinformation, disinformation and outright lies about that. And that's really unfortunate.

MARGARET BRENNAN: You're angry about it.

DR. FAUCI: Well, you know, my concern that I keep saying is that my job is to do what I can as a scientist to preserve and protect the health of the American public and indirectly, in many respects, the health of the world because our country is a leader in science. A leader in health. A leader in the kinds of things- Where did these vaccines come from that are saving millions of people? They came from us. That's my job. The politicization of it is really unfortunate because as I've said, I've stayed away from politics my entire life. I am somebody who only cares about science and health, and it is- you're right, it's painful and disturbing to see when you're trying to focus all of your attention on doing what you can do the way we did to create the vaccines, to develop the drugs, to save millions of lives. And then you have this completely outlandish politicization of it. Politicization of everything. Politicization of the public health, politicization of the origins, politicization of all of it is really- I think when we look back at this, we're going to see what were we thinking, what was going on back then?

MARGARET BRENNAN: The- two *Washington Post* reporters said that back in July of 2020, you had been speaking to your wife about resigning.

DR. FAUCI: I never spoke to my wife, ever about resigning. They got that wrong. I never even considered for a moment of resigning.

MARGARET BRENNAN: Never considered it for a moment?

DR. FAUCI: Not even for a second.

MARGARET BRENNAN: Dr. Birx told us she thought about it almost daily, ultimately didn't but-

DR. FAUCI: Dr. Birx is Dr. Birx and Tony Fauci is Tony Fauci.

MARGARET BRENNAN: Why do you feel so strongly about that, about staying on the job when you become, I mean, you were personally not just rhetorically threatened, your security, your safety, your family? How did you deal with that?

DR. FAUCI: I dealt with it by focusing on what my job is from the time that I went into medicine to right now, where I am at my age, my job has been totally focused on doing what I can with the talents and the influence I had to make scientific advances to protect the health of the American public. So anybody who spins lies and threatens and all that theater that goes on with some of the investigations and the congressional committees and the Rand Paul's and all that other nonsense, that's noise, MARGARET, that's noise. I know what my job is.

MARGARET BRENNAN: Senator Cruz told the attorney general you should be prosecuted.

DR. FAUCI: Yeah. I have to laugh at that. I should be prosecuted? What happened on Jan. 6, senator?

MARGARET BRENNAN: Do you think that this is about making you a scapegoat to deflect--

DR. FAUCI: Of course-

MARGARET BRENNAN: --From President Trump?

DR. FAUCI: Of course, you have to be asleep not to figure that one out.

MARGARET BRENNAN: Well, there are a lot of Republican senators taking aim at this. I mean--

DR. FAUCI: That's OK, I'm just going to do my job and I'm going to be saving lives and they're going to be lying.

MARGARET BRENNAN: It just, it seems, another layer of danger to play politics around matters of life and death.

DR. FAUCI: Right, exactly. Exactly. And to me, that's- that's unbelievably bad because all I want to do is save people's lives. That's what I have done for the last 50 years, 40 of which was 37 of which was leading the institute. And when I see people who scattered around misinformation and lies that can actually endanger the lives of people, but also it is very easy to pick out an individual and make them a target because that's what people can focus on. But

you're talking about systems, you're talking about the CDC, you're talking about the FDA, you're talking about science in general. So if they want to- I mean, anybody who's looking at this carefully realizes that there's a distinct anti-science flavor to this. So if they get up and criticize science, nobody's going to know what they're talking about. But if they get up and really aim their bullets at Tony Fauci, well, people could recognize there's a person there. There's a face, there's a voice you can recognize, you see him on television. So it's easy to criticize, but they're really criticizing science because I represent science. That's dangerous. To me, that's more dangerous than the slings and the arrows that get thrown at me. I'm not going to be around here forever, but science is going to be here forever. And if you damage science, you are doing something very detrimental to society long after I leave. And that's what I worry about.

MARGARET BRENNAN: And in real world terms, what does that mean? Does that mean you fear vaccination rates go down? Does that mean the next national emergency people just don't listen to the doctors. What- what do you mean?

DR. FAUCI: Yeah, what I'm concerned about is that if you put science aside and if you discredit science, you start to discredit the truth of what it takes to get people their health preserved, prevent disease, treat disease. When you do that, you are going to really disrupt society in very many respects, and that's what I worry about. I mean, anybody who looks at what's going on in the United States to say there's not a lot of- lies become normalized now, and the social media amplifies the normalisation of lies. So scientists try to say this is the truth, and it's based on data. That's what we live by, data, evidence, truth. And then you all of a sudden have permeating in society, it is OK to say anything you want that is patently, obviously wrong. And if you say it long enough and often enough and you get social media involved, then everybody- not everybody, X percent of the population starts believing it. See, that's what I worry about more than people throwing slings and arrows at me because my whole life has been as a scientist and I identify with the field of health and science. And if you're attacking me, you're really attacking science. I mean, everybody knows that.

MARGARET BRENNAN: You told my colleague Ted Koppel that you would not retire until you get COVID in the rearview mirror?

DR. FAUCI: That is correct.

MARGARET BRENNAN: What does that look like? What does rear view mirror look like?

DR. FAUCI: Rearview mirror looks like when you and I are talking some time on an interview whenever, and we're talking about something else and that COVID is not dominating the economy, the- the mental framework of our society. Dominating our fear of being safe for ourselves and our children. That's what it means in the rear view mirror. Not that we've accepted something that's still terrible, but that it's so low that we can start thinking about other things that are much more important.

MARGARET BRENNAN: We've been through a national trauma as a country.

DR. FAUCI: Right.

MARGARET BRENNAN: How have you processed what you personally have been through, for the past almost two years?

DR. FAUCI: You know, it hasn't been easy I- you know with- the things that I really don't like a lot is the fact that not only me, but my colleagues, when you say something like you need to get vaccinated, to protect yourself, your family and to- and to really fulfill your societal responsibility to keep the community safe. And for that, I get death threats. And for that, I get my family, my wife and my three daughters harassed. That makes me say society has really got a problem. So I've- I've never been someone who is ego-centric, I don't think about what effect it has on me. You know, I worry about what effect it is having on our democracy and our society, that's what I worry about much more. I'm going to be fine, you know, I'm going to be fine. I joke around with people who know me. I grew up in the Bensonhurst section of Brooklyn. I'm going to be fine. I don't worry about people who throw these lies around. I worry about what impact it's going to have on society.

MARGARET BRENNAN: I think the country doesn't know how to process this right now. You look at overdose deaths, you look at, you know, drinking, you look at all the like, all the things that our country has suffered through this pandemic. Is there a playbook that you are handing over to the next person right behind you at the NIH when that retirement day does come?

DR. FAUCI: Yeah, the playbook for them is to do what I'm doing now, no matter what nonsense, politicization and everything throws at you. Focus on what your goal is and your goal is to end an outbreak by what you have at your disposal. And what we have at our disposal is science, which has led to a highly effective vaccine and soon to be a

number of highly effective drugs. And just phase out everything else. If you get caught up in this nonsense of politicization, you're not going to be able to do your job as well. So that's the reason why when all of these things come in, when they pass a law with my name on it, when Joe Schmo says I should retire, I should go to jail. I look at that and I go, forget that. I know what my job is.

MARGARET BRENNAN: For you and your family, I know you've said your daughter's worried about exposing you. You didn't gather with them last year around holidays. This year going into the holidays, how do you advise people? What do they do to safely gather with their family? And are you gathering with your family?

DR. FAUCI: Yes, I am. I mean, not for Thanksgiving, only for logistic purposes. My daughters are in three separate cities, triangulated throughout the country and they have jobs and to fly all the way in just for a day. But we're all getting together for Christmas, for sure. The whole family, including the dogs.

MARGARET BRENNAN: And that's- how do you do that safely?

DR. FAUCI: You get vaccinated and you get boosted getting back to the beginning of a conversation, you get vaccinated. You surround yourself with vaccinated people and you get boosted. And when you're in a congregate setting outside of the family setting, you wear a mask because you're not sure what the status of these people are. So I am going to be in my home, with my wife, with my daughters and with their partners, and we're going to be sitting around maskless, enjoying a Christmas and Christmas Eve.

MARGARET BRENNAN: Do you- do you test going into the gathering and on the way back out? What should people do?

DR. FAUCI: Well, it depends. I think- I mean, my daughters are very careful because of my age. You know, I'm not exactly the youngest person around here and they're concerned about me, even though I'm vaccinated. So what they generally do and I think they'll do this is even though they're vaccinated and boosted with they will likely do is to get tested 48 hours, 24 hours before they come home because they're going to have to make a trip to fly, be in an airport, get on a plane and just to make doubly sure they're going to get one of those home test and test.

MARGARET BRENNAN: And on the way back, they'll do the same?

DR. FAUCI: I would think so, yeah. And that's the reason why, getting back to what I said during 2020, when I said we need to flood the system with testing, I've said that more than once.

MARGARET BRENNAN: And are we there yet because you hear frequently--

DR. FAUCI: No, we're doing- we're getting there, no-

MARGARET BRENNAN: The at home tests are even hard to find.

DR. FAUCI: Now give credit to President Biden where we can. He's invested billions of dollars to get as low as 200 million tests a month and as high as a half a billion tests a month. So the Fauci plea to flood the system with testing is going to happen for sure.

MARGARET BRENNAN: Do you feel traumatized by the past two years?

DR. FAUCI: No, no. I really am very moved by people who are concerned about me, well-meaning people. Maybe even yourself, sincerely concerned about me. But when you focus on what your job is and your job is to save people's lives, you don't have any time to get traumatized. I mean, I don't- I just don't have any time to be thinking about traumatizing. I work- I haven't had a day off in 20 months, and it doesn't bother me because we're doing things that are saving lives. That's really important. That's why I went to medical school and 50 years later, I'm doing it.

MARGARET BRENNAN: Do you- in this playbook, you're handing off to your future successor, do you say the next pandemic comes out as faster? It comes more frequently. I've had World Health Organization scientists say because of things like environmental changes, we're going to have more of these coming at us faster.

DR. FAUCI: You know, I think we likely will, though you can't predict, you know, I've been through multiple, multiple emergencies of diseases. Some have been one off trivial, doesn't mean anything. And you know, there- but for the grace of God, a little change in a mutation could have made it do something a little bit differently. But I think the- the idea of the human animal interface is something that we've really got to address that. You know, that's the reason why I get back to the fact of these wet markets that bring in animals that are next to bats, in caves, in wherever, who knows, all in Southeast Asia, in China.

MARGARET BRENNAN: You want more regulation of those internationally?

DR. FAUCI: I want that to be regulated. I really, really do. And we know the Chinese were trying to regulate that. But there were people who were breaking the law and there was good documentation from people who

photographed that- that animals that were not supposed to be brought in from the wild into the wet markets were there. They were breaking the law. And I think that's the reason why when this happened, I don't know, but I think why the Chinese just completely cleaned it out. We're not supposed to be doing that. I think that is one of the reasons why we're not able to find out what the original source was. I think they've destroyed some of the evidence.

MARGARET BRENNAN: So when the PLA, when the Chinese army comes in, they're the first line of control versus the Chinese CDC. You don't think that's about intentionally covering things up, you're painting a scenario there where it's just trying to clean up the mess as quick as possible.

DR. FAUCI: Yeah, the experience with China is even when they have nothing to hide, they're acting suspicious. No, it is. That's the truth. I mean, that is the truth. They're very, very much that they just don't- whenever there's an outbreak, they just want to be able to say it's nothing to do. And even when they've done nothing wrong, they act suspicious.

MARGARET BRENNAN: All right, Dr. Fauci, I know we've taken a lot of your time. Thank you for making it.

DR. FAUCI: My pleasure.

Abridgement 1: FDA's discussion of the effective administration of COVID-19

Convalescent Plasma which outlines: (1) the concentration of exogenous CCP
(2) the timing of administration of exogenous CCP during the viremic phase of COVID-19, and
(3) the individual human's endogenous immunological response to the infection

... The observation that high titer CCP was beneficial when administered within 72 hours of symptom onset in high risk subjects, but failed to demonstrate benefit in trials where the median duration of symptoms was 8 days or longer, indicates benefit with CCP transfusion is more likely in patients early in the humoral immune response when host antibody titers remain undetectable or low (i.e., likely within the first week following symptom onset). This is consistent with longstanding historical precedent in passive immune therapies for viral infections, where prophylactic or early use has generally been more effective than in established infections[34].

These trends are also consistent with clinical evidence for administration of anti-SARS-CoV-2 monoclonal antibodies, where benefit has been demonstrated with early outpatient use, but not in hospitalized patients within 12 days of symptom onset[35-37] as described in the following two studies:

In outpatient studies of bamlanivimab in recently diagnosed patients with mild to moderate disease (BLAZE-1)[36], subjects were excluded if they were previously known to be seropositive. Subjects had a median of 4 days of symptoms at the time of infusion, and the study found one of three doses of neutralizing antibody LY-CoV555 appeared to accelerate the natural decline in viral load over time. While reduction in viral load was the primary endpoint in this phase 2 trial, subjects treated with bamlanivimab also showed a nominally statistically significant reduction in COVID-19 related hospitalizations or ED visits within 28 days in the pooled dose-level data.

In outpatient studies of casirivimab/imdevimab in symptomatic patients with mild to moderate COVID-19 (R10933-10987-COV-2067), subjects who were no more than 7 days from symptom enrollment were included regardless of serostatus[35]. Casirivimab/imdevimab treatment reduced viral load, and patients who were seronegative at baseline showed larger reductions in viral load and a larger reduction in the proportion of subjects with at least one medically attended visit compared to the overall population. Based on these studies, both therapies were granted EUA for use in high risk outpatients with mild to moderate COVID-19 (<https://www.fda.gov/media/143892/download>, <https://www.fda.gov/media/143603/download>).

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In early studies of the COVID-19 pandemic, the median time from symptom onset to the development of dyspnea was approximately 5-8 days[38, 39], and patients who develop critical illness typically do so shortly thereafter (days 8-10)[40]. While the study by Libster et al[10] demonstrated a reduction in progression to severe disease in high risk outpatients within 72 hours of the onset of symptoms, one factor complicating very early use of CCP in the outpatient population is the evidence that a large proportion of these patients will have a self-limited illness and will not go on to severe or critical illness even without targeted intervention[41]. Therefore, in the early-disease outpatient population, it is important to have a full understanding of the relative benefit and identify high-risk populations so that the known and potential risks of transfusion are outweighed by the known and potential benefits of CCP. Ongoing randomized controlled trials will be critical to determine the clinical and laboratory parameters that can identify where the potential benefit of CCP outweighs the potential risk in outpatients.

Based on the study by Libster et al[10] the therapeutic window appears to be at least within 72

hours of symptom onset, while additional negative RCTs with a median duration of symptoms prior to transfusion of 8 days indicating that 8 days after symptom onset may be too late for efficacy of CCP in immunocompetent hospitalized COVID-19 patients. These timepoints appear to correlate with the timing of the patients' own antibody responses to infection, such that by the time a patient is forming their own antibodies, benefit from CCP appears unlikely. The time period between 3 and 7 days remains to be studied rigorously in randomized trials of CCP, but observational studies, preclinical studies, studies of related therapies, and what is known about the timing of the adaptive immune response in SARS-CoV-2 infection suggest that high titer CCP may be effective in this window period. As noted above, this window appears to be longer in the setting of impaired or deficient humoral immunity. Nonetheless, adequate and well controlled trials in this time period remain necessary for a conclusive demonstration of efficacy....

<https://www.fda.gov/media/141480/download>

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The official EUA after the *White House* Press conference August 23, 2020 was first captured by the *Internet Archive* on August 24, 2020:

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